

Issued in Renton, Washington, on August 13, 2014.

**Jeffrey E. Duven,**

*Manager, Transport Airplane Directorate,  
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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA-2014-0077; Directorate Identifier 2013-CE-021-AD; Amendment 39-17941; AD 2014-16-17]**

**RIN 2120-AA64**

#### **Airworthiness Directives; Air Tractor, Inc. Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2010-17-18 R1, which applies to certain Air Tractor, Inc. Models AT-802 and AT-802A airplanes. AD 2010-17-18 R1 required repetitively inspecting (using the eddy current method) the two outboard fastener holes in both of the wing main spar lower caps at the center splice joint for cracks; repairing or replacing any cracked spar; changing the safe life for certain serial number ranges; and sending the inspection results, only if cracks are found, to the FAA. This new AD retains all actions of AD 2010-17-18 R1 and expands the applicability to include all serial numbers regardless of configuration or operational use. This AD was prompted by our determination that the safe life for the wing main spar lower caps should apply to all Models AT-802 and AT-802A airplanes regardless of configuration or operational use. We are issuing this AD to correct the unsafe condition on these products.

**DATES:** This AD is effective September 29, 2014.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 9, 2010 (75 FR 52255, August 25, 2010).

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of April 21, 2006 (71 FR 19994, April 19, 2006).

**ADDRESSES:** For service information identified in this AD, contact Air Tractor, Inc., P.O. Box 485, Olney, Texas 76374; telephone: (940) 564-5616; fax:

(940) 564-5612; email: [airmail@airtractor.com](mailto:airmail@airtractor.com); Internet: [www.airtractor.com](http://www.airtractor.com). You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

#### **Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0077; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

#### **FOR FURTHER INFORMATION CONTACT:**

Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308-3365; fax: (210) 308-3370; email: [andrew.mcanaul@faa.gov](mailto:andrew.mcanaul@faa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2010-17-18 R1, Amendment 39-16552 (75 FR 82219, December 30, 2010) (“AD 2010-17-18 R1”), for certain Air Tractor, Inc. Models AT-802 and AT-802A airplanes. The NPRM published in the **Federal Register** on February 12, 2014 (79 FR 8350). The NPRM was prompted by our determination that the safe life for the wing main spar lower caps should apply to all Models AT-802 and AT-802A airplanes regardless of configuration or operational use. The NPRM proposed to continue to require repetitively inspecting (using the eddy current method) the two outboard fastener holes in both of the wing main spar lower caps at the center splice joint for cracks; repairing or replacing any cracked spar; changing the safe life for certain serial number ranges; and sending the inspection results, only if cracks are found, to the FAA. The NPRM also proposed to expand the applicability to include all serial numbers regardless of configuration or operational use. We are issuing this AD

to correct the unsafe condition on these products.

#### **Comments**

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the NPRM (79 FR 8350, February 12, 2014) and the FAA’s response to that comment.

#### **Request To Withdraw Proposed Rulemaking**

David Ligon of Air Tractor, Inc. requested the FAA to withdraw the proposed AD.

David Ligon stated that he (Air Tractor, Inc.) believes the FAA does not have relevant information or objective evidence to establish that an unsafe condition is likely to exist or develop in Models AT-802 and AT-802A air tanker (fire-fighting) airplanes. Air Tractor, Inc. stated that the safe life of the wing on the land-based Models AT-802 and AT-802A air tanker airplanes far exceeds that of their agricultural application counterparts and will continue to work to establish an appropriate wing safe life.

Included with the comment from Air Tractor, Inc. were two graphs showing firebomber and agricultural airplane exceedance curves from a single Model AT-802 air tanker airplane, their validated Model AT-802 agricultural application airplane spectrum, and one set of generic air tanker and agricultural application exceedance curves from Report No. DOT/FAA/AR-05/035, Consolidation and Analysis of Loading Data in Firefighting Operations: Analysis of Existing Data and Definition of Preliminary Air Tanker and Lead Aircraft Spectra, which can be found on the Internet at <http://www.tc.faa.gov/its/worldpac/techrpt/ar05-35.pdf>, and FAA Advisory Circular 23-13A, which can be found on the internet at [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgAdvisoryCircular.nsf/0/CCAE8A15127D66408625708C00710BA4?OpenDocument&Highlight=23-13a](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/CCAE8A15127D66408625708C00710BA4?OpenDocument&Highlight=23-13a), respectively.

Air Tractor, Inc. does not disagree that there is a need to establish a safe life for the wing main spar lower caps on all airplanes regardless of configuration or operational use. Air Tractor, Inc. also stated that they are concerned that issuing this AD will result in unneeded additional cost to the industry that could possibly hinder the establishment of an appropriate wing safe life in the future.

We do not agree with the commenter. The wing main spar centerline joint is a design detail that has demonstrated in-

service fatigue cracking on Models AT-802 and AT-802A agricultural application airplanes. We have determined that this design detail shows a demonstrated risk that fatigue cracking is expected to also occur on the same type design airplanes used for other purposes such as fire-fighting and patrolling. The guidance for addressing known safety risk through a fatigue management program that includes establishing appropriate inspection, modification, and/or life limits is outlined in the appendices of FAA Advisory Circular 91-82A, which can be found on the Internet at [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgAdvisoryCircular.nsf/0/A07DDCB245AD6B43862578F8006F82E9?OpenDocument&Highlight=91-82a](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/A07DDCB245AD6B43862578F8006F82E9?OpenDocument&Highlight=91-82a). These aspects are currently addressed for the agricultural application Models AT-802 and AT-802A airplanes in AD 2010-17-18 R1. We believe it is appropriate to expand the applicability of AD 2010-17-18 R1 to include all Models AT-802 and AT-802A airplanes used in other operational roles since they have the same type design detail and share the same demonstrated risk.

We have not received validated data from Air Tractor, Inc. that provides inspection intervals, modification times, or safe life limits for the Models AT-802 and AT-802A airplanes wing main spar for operational usages other than for agricultural application. The exceedance data provided by Air Tractor, Inc. does not provide those inspection intervals, modification times, or life limit replacement times. Report No. DOT/FAA/AR-05/035, which can be found on the Internet at [http://](http://www.tc.faa.gov/its/worldpac/techrpt/ar05-35.pdf)

[www.tc.faa.gov/its/worldpac/techrpt/ar05-35.pdf](http://www.tc.faa.gov/its/worldpac/techrpt/ar05-35.pdf), includes exceedance data for air tanker (fire-fighting) airplanes of various weights. The data shows a trend of increasing severity in the flight spectrum as airplane size and gross weight decrease. In Report No. DOT/FAA/AR-05/035, the exceedance data does not include airplanes having a gross weight as low as Models AT-802 and AT-802A airplanes; therefore, the exceedance data may not be representative of the lighter gross weight AT-802/802A air tanker airplane fleet. Additionally, limited exceedance curves we received earlier from Air Tractor, Inc. include data for one land-based and two float-equipped Model AT-802 air tanker airplanes. The two float-equipped airplane's exceedance curves closely match the severity of the validated Model AT-802 airplane agricultural application exceedance curves. We question why the two float-equipped airplanes have a more severe spectrum than the single land-based Model AT-802 air tanker airplane. We would expect the float-equipped airplanes to be less maneuverable, and therefore less severely flown than their land-based counterpart.

We agree with the need to establish life limits for the Models AT-802 and AT-802A air tanker fleet, as well as those used in other operations such as patrolling. Further, we evaluated the information presented by Air Tractor and determined it is appropriate to apply the same inspections, modification, and safe life limitations addressed in the current AD to Models AT-802 and AT-802A airplanes engaged in other operational roles. We arrived at this decision based on (1) the

time in service those fleets have now accumulated, and (2) because they have the same wing main spar design feature as the agricultural applications airplanes and share the same demonstrated safety risk.. We remain open to working with Air Tractor, Inc. to obtain data that reflects an adequate pilot mix and operational conditions, that appropriately differentiates Models AT-802 and AT-802A airplane wing main spar inspection and modification times, and includes a safe life based on operational usage.

We are not changing the final rule AD action based on this comment.

**Conclusion**

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (79 FR 8350, February 12, 2014) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 8350, February 12, 2014).

**Costs of Compliance**

We estimate that this AD affects 154 airplanes of U.S. registry.

We estimate the following costs to comply with this AD. However, the only difference in the costs presented below and the costs associated with AD 2010-17-18 R1 is the addition of 33 airplanes, from 121 to 154, and the corresponding costs associated with those 33 airplanes:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Eddy current inspection .....	\$500 to \$800 .....	Not Applicable .....	\$500 to \$800 .....	\$77,000 to \$123,200.
Spar cap replacement (two spars).	495 work-hours × \$85 per hour = \$42,075.	\$39,100 (two spars) .....	\$81,175 .....	\$12,500,950.

We estimate the following costs to do any necessary repairs/modifications that

will be required based on the results of the inspections. We have no way of

determining the number of aircraft that might need these repairs/modifications:

**ON-CONDITION COSTS**

Action	Labor cost	Parts cost	Cost per product
Center splice plate installation .....	185 work-hours × \$85 per hour = \$15,725 .....	\$4,300 .....	\$20,025
Extended splice block installation .....	70 work-hours × \$85 per hour = \$5,950 .....	3,200 .....	9,150
Cold-work lower spar cap fastener holes .....	16 work-hours × \$85 per hour = \$1,360 .....	Not Applicable .....	1,360

### Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120-0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591. ATTN: Information Collection Clearance Officer, AES-200.

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

### Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2010-17-18 R1, Amendment 39-16552 (75 FR 82219, December 30, 2010), and adding the following new AD:

**2014-16-17 Air Tractor, Inc.:** Amendment 39-17941; Docket No. FAA-2014-0077; Directorate Identifier 2013-CE-021-AD.

#### (a) Effective Date

This AD is effective September 29, 2014.

#### (b) Affected ADs

This AD supersedes AD 2010-17-18 R1, Amendment 39-16552 (75 FR 82219, December 30, 2010, ("AD 2010-17-18 R1")).

#### (c) Applicability

This AD applies to Air Tractor, Inc. Models AT-802 and AT-802A airplanes, all serial numbers, that are certificated in any category.

#### (d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 57: Wings.

#### (e) Unsafe Condition

This AD was prompted by our determination that there is a need to establish a safe life for the wing main spar lower caps on all airplanes regardless of configuration or operational use. We are issuing this AD to detect and correct cracks in the wing main spar lower cap at the center splice joint, which could result in failure of the spar cap and lead to wing separation and loss of control of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified in paragraphs (g) through (l) of this AD, including all subparagraphs, unless already done (compliance with AD 2010-17-18 R1).

### (g) Actions for Airplanes Serial Numbers (SNs)—0001 Through—0091

(1) Eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks at the compliance times specified in paragraphs (g)(1)(i) or (g)(1)(ii) of this AD. Do the inspections following Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002.

(i) *For airplanes previously affected by AD 2010-17-18 R1:* Initially inspect upon reaching 1,700 hours time-in-service (TIS) or within the next 50 hours TIS after April 21, 2006 (the effective date retained from AD 2006-08-09, Amendment 39-14565 (71 FR 19994, April 19, 2006; corrected 71 FR 27794, May 12, 2006)), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 800 hours TIS unless you installed the center splice plate and extended 8-bolt splice blocks before September 9, 2010 (the effective date retained from AD 2010-17-18, Amendment 39-16412 (75 FR 52255, August 25, 2010), "AD 2010-17-18"), then repetitively inspect following the compliance times in paragraphs (g)(5)(i) through (g)(5)(iii) of this AD.

(ii) *For airplanes not previously affected by AD 2010-17-18 R1:* Initially inspect upon reaching 1,700 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 800 hours TIS unless you installed the center splice plate and extended 8-bolt splice blocks before September 29, 2014 (the effective date of this AD), then repetitively inspect following the compliance times in paragraphs (g)(6)(i) through (g)(6)(iii) of this AD.

(2) If any cracks are found as a result of any inspection required in paragraph (g)(1) of this AD, before further flight after the inspection where a crack was found, do the actions specified in paragraphs (g)(2)(i) or (g)(2)(ii) of this AD. If you repair your airplane following paragraph (g)(2)(i) of this AD before the airplane reaches a total of 3,200 hours TIS, you must do the eddy current inspections following the compliance times in paragraphs (g)(5) and (g)(6) of this AD, as applicable. If you repair your airplane following paragraph (g)(2)(i) of this AD at 3,200 hours TIS or after, this repair terminates the repetitive inspections required in this AD.

(i) For cracks that can be removed by repair, install center splice plate, P/N 20997-2, and extended 8-bolt splice blocks, P/N 20985-1/-2, cold-work the lower spar cap fastener holes, and eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks. This eddy current inspection is required as part of the modification and is separate from the inspections required in paragraph (g)(1) of this AD. Incorporating this repair modification extends the safe life of the wing main spar lower cap to a total of 8,000 hours TIS. Do the repair following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co.

Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Drawing Number 20995, Sheet 2, Rev. D, dated November 25, 2005; and Snow Engineering Co. Service Letter #240, dated September 30, 2004.

(ii) For cracks that cannot be repaired by incorporating the repair modification specified in paragraph (g)(2)(i) of this AD, replace the lower spar caps and associated parts listed following paragraph (g)(3) of this AD.

(3) Replace the wing main spar lower caps, the web plates, the center joint splice blocks and hardware, and the wing attach angles and hardware, and install the steel web splice plate at whichever of the compliance times specified in paragraphs (g)(3)(i), (g)(3)(ii), or (g)(3)(iii) of this AD that occurs first. If the wing main spar lower cap was replaced with P/N 21118-1/-2, the new spar safe life is 11,700 hours TIS. If the wing main spar lower cap is replaced with P/N 21083-1/-2 before September 9, 2010 (the effective date retained from AD 2010-17-18), the safe life for that P/N spar cap is 8,000 hours TIS until the wing main spar lower cap is replaced with P/N 21118-1/-2. This replacement terminates the inspections required in this AD. Do the replacement following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Service Letter #80GG, revised December 21, 2005; and Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A, dated January 7, 2009.

(i) *For all airplanes:* Before further flight when cracks are found that cannot be repaired by incorporating the repair modification specified in paragraph (g)(2)(i) of this AD.

(ii) *For airplanes previously affected by AD 2010-17-18 R1:* Before or when the airplane reaches the wing main spar lower cap safe life of a total of 4,100 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later.

(iii) *For airplanes not previously affected by AD 2010-17-18 R1:* Before or when the airplane reaches the wing main spar lower cap safe life of a total of 4,100 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later.

(4) To extend the initial 4,100-hour TIS safe life of the wing main spar lower cap to a total of 8,000 hours TIS, you may incorporate the repair modification specified in paragraph (g)(2)(i) of this AD between 3,200 hours TIS and 4,100 hours TIS. This modification terminates the repetitive inspections required in paragraphs (g)(1)(i) and (g)(1)(ii) of this AD, unless you do the modification before the airplane reaches a total of 3,200 hours TIS to repair cracks.

(5) *For airplanes previously affected by AD 2010-17-18 R1:* If you modified your airplane to repair cracks before the airplane reached a total of 3,200 hours TIS, as required in paragraph (g)(2)(i) of this AD, or you previously modified your wing to extend the safe life but did not cold work the lower spar cap fastener holes, you must do the eddy

current inspections required in paragraph (g)(1) of this AD following the compliance times specified in paragraphs (g)(5)(i) through (g)(5)(iii) of this AD, as applicable.

(i) If the airplane already had the center splice plate and extended 8-bolt splice blocks installed at or after 3,200 hours TIS but the fastener holes have not been cold worked, you may cold work the fastener holes at any time to terminate the repetitive inspection requirements of this paragraph. Initially inspect when the airplane reaches a total of 2,400 hours TIS after the modification or within the next 100 days after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 1,200 hours TIS until the 8,000 hours TIS spar replacement time.

(ii) If the airplane already had the center splice plate and extended 8-bolt splice blocks already installed before reaching 3,200 hours TIS but the fastener holes have not been cold worked, initially inspect when the airplane reaches a total of 2,400 hours TIS after the modification or within the next 100 days after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 1,200 hours TIS. Upon reaching 4,800 hours TIS after the modification, repetitively thereafter inspect at intervals not to exceed 600 hours TIS until the 8,000 hours TIS spar replacement time.

(iii) If the airplane had the center splice plate and extended 8-bolt splice blocks installed before reaching 3,200 hours TIS and the fastener holes have been cold worked, initially inspect when the airplane reaches a total of 4,800 hours TIS after the modification or within the next 100 days after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 600 hours TIS until the 8,000 hours TIS spar replacement time.

(6) *For airplanes not previously affected by AD 2010-17-18 R1:* If you modified your airplane to repair cracks before the airplane reached a total of 3,200 hours TIS, as required in paragraph (g)(2)(i) of this AD, or you previously modified your wing to extend the safe life but did not cold work the lower spar cap fastener holes, and you, you must do the eddy current inspections required in paragraph (g)(1) of this AD following the compliance times specified in paragraphs (g)(6)(i) through (g)(6)(iii) of this AD, as applicable.

(i) If the airplane already had the center splice plate and extended 8-bolt splice blocks installed at or after 3,200 hours TIS but the fastener holes have not been cold worked, you may cold work the fastener holes at any time to terminate the repetitive inspection requirements of this paragraph. Initially inspect when the airplane reaches a total of 2,400 hours TIS after the modification or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 1,200 hours TIS until the 8,000 hours TIS spar replacement time.

(ii) If the airplane had the center splice plate and extended 8-bolt splice blocks

already installed before reaching 3,200 hours TIS but the fastener holes have not been cold worked, initially inspect when the airplane reaches a total of 2,400 hours TIS after the modification or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later.

Repetitively thereafter inspect at intervals not to exceed 1,200 hours TIS. Upon reaching 4,800 hours TIS after the modification, repetitively thereafter inspect at intervals not to exceed 600 hours TIS until the 8,000 hours TIS spar replacement time.

(iii) If the airplane had the center splice plate and extended 8-bolt splice blocks installed before reaching 3,200 hours TIS and the fastener holes have been cold worked, initially inspect when the airplane reaches a total of 4,800 hours TIS after the modification or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 600 hours TIS until the 8,000 hours TIS spar replacement time.

(7) If you find any cracks during any inspection required by paragraphs (g)(5) and (g)(6) of this AD, before further flight, replace the lower spar caps and the associated parts following the procedures identified in paragraph (g)(3) of this AD.

#### (h) Actions for Airplanes SNs-0092 Through -0101

(1) Eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks at the compliance times specified in paragraphs (h)(1)(i) or (h)(1)(ii) of this AD. Do the inspections following Snow Engineering Co. Service Letter #284, dated October 4, 2009; and Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002.

(i) *For airplanes previously affected by AD 2010-17-18 R1:* Initially inspect upon reaching 1,700 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 800 hours TIS unless the center splice plate, P/N 20994-2, is installed, then repetitively inspect at intervals not to exceed 2,000 hours TIS.

(ii) *For airplanes not previously affected by AD 2010-17-18 R1:* Initially inspect upon reaching 1,700 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 800 hours TIS unless the center splice plate, P/N 20994-2, is installed, then repetitively inspect at intervals not to exceed 2,000 hours TIS.

(2) If any cracks are found as a result of any inspection required by paragraph (h)(1) of this AD, before further flight after the inspection where a crack was found, do the actions specified in paragraphs (h)(2)(i) or (h)(2)(ii) of this AD.

(i) For cracks that can be removed by repair, install the 9-bolt splice blocks, cold-work the lower spar cap fastener holes, install the center splice plate, P/N 20994-2,

if not already installed, and eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks. This eddy current inspection is required as part of the repair and is separate from the inspections required in paragraph (h)(1) of this AD. Incorporating this repair modification extends the safe life of the wing main spar lower cap to a total of 8,000 hours TIS and terminates the repetitive inspections required in this AD. Do the repair following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Service Letter #281, dated August 1, 2009; and Snow Engineering Co. Drawing Number 20995, Sheet 3, dated November 25, 2005.

(ii) For cracks that cannot be repaired by incorporating the repair modification specified in paragraph (h)(2)(i) of this AD, replace the lower spar caps and associated parts listed following paragraph (h)(3) of this AD.

(3) Replace the wing main spar lower caps, the web plates, the center joint splice blocks and hardware, and the wing attach angles and hardware, and install the steel web splice plate at whichever of the compliance times specified in paragraphs (h)(3)(i), (h)(3)(ii), or (h)(3)(iii) of this AD that occurs first. If the wing main spar lower cap is replaced with P/N 21118-1/-2, the new spar safe life is 11,700 hours TIS. If the wing main spar lower cap was replaced with P/N 21083-1/-2 before September 9, 2010 (the effective date retained from AD 2010-17-18), the safe life for that P/N spar cap is 8,000 hours TIS until the wing main spar lower cap is replaced with P/N 21118-1/-2. This replacement terminates the inspections required in this AD. Do the replacement following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Service Letter #80GG, revised December 21, 2005; and Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A, dated January 7, 2009.

(i) For all airplanes: Before further flight when cracks are found that cannot be repaired by incorporating the modification specified in paragraph (h)(2)(i) of this AD.

(ii) For airplanes previously affected by AD 2010-17-18 R1: Before or when the airplane reaches the wing main spar lower cap safe life of a total of 4,100 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later.

(iii) For airplanes not previously affected by AD 2010-17-18 R1: Before or when the airplane reaches the wing main spar lower cap safe life of a total of 4,100 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later.

(4) To extend the initial 4,100-hour TIS safe life of the wing main spar lower cap to a total of 8,000 hours TIS, before the airplane reaches a total of 4,100 hours TIS, as long as no cracks are found during any inspection required in paragraph (h)(1) of this AD, install center splice plate, P/N 20994-2, if

not already installed as part of a repair, cold-work the lower spar cap fastener holes, and eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks. This eddy current inspection is required as part of the modification and is separate from the inspections required in paragraph (h)(1) of this AD. After installing P/N 20994-2, eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks repetitively at intervals not to exceed 2,000 hours TIS following the procedures specified in paragraph (h)(1) of this AD. Do the modification following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A., dated January 7, 2009; and Snow Engineering Co. Service Letter #245, dated April 25, 2005.

(i) For airplanes previously affected by AD 2010-17-18 R1: As of September 9, 2010 (the effective date retained from AD 2010-17-18), if you have already exceeded the 4,100-hour TIS threshold for extending the safe life to 8,000 hours TIS, you may be eligible for an alternative method of compliance following paragraph (o) in this AD.

(ii) For airplanes not previously affected by AD 2010-17-18 R1: As of September 29, 2014 (the effective date of this AD), if you have already exceeded the 4,100-hour TIS threshold for extending the safe life to 8,000 hours TIS, you may be eligible for an alternative method of compliance following paragraph (o) in this AD.

(5) If any cracks are found as a result of the eddy current inspection required by paragraph (h)(4) of this AD, do the actions specified in paragraphs (h)(5)(i) or (h)(5)(ii) of this AD.

(i) For cracks that can be removed by repair, install the 9-bolt splice blocks, cold-work the lower spar cap fastener holes, and eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks. This eddy current inspection is required as part of the modification and is separate from the inspections required in paragraph (h)(1) of this AD. Incorporating this repair modification terminates the repetitive inspections required in paragraph (h)(4) of this AD. Do the repair following Snow Engineering Co. Service Letter #284, dated October 4, 2009; and Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Service Letter #281, dated August 1, 2009; and Snow Engineering Co. Drawing Number 20995, Sheet 3, dated November 25, 2005.

(ii) For cracks that cannot be repaired by incorporating the repair modification specified in paragraph (h)(5)(i) of this AD, replace the lower spar caps and associated parts listed following paragraph (h)(3) of this AD.

#### (i) Actions for Airplanes SNs-0102 through -0178

(1) For airplanes previously affected by AD 2010-17-18 R1: Eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks at the compliance times specified in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD, as applicable. Do the inspections following Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Service Letter #245 dated April 25, 2005; Snow Engineering Co. Service Letter #284, dated October 4, 2009.

(i) If the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps have not been cold worked, initially inspect when the airplane reaches a total of 5,500 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 1,100 hours TIS until the 8,000 hours TIS spar replacement time.

(ii) If the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps have been cold worked, initially inspect when the airplane reaches a total of 5,500 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 2,200 hours TIS until the 8,000 hours TIS spar replacement time.

(2) For airplanes not previously affected by AD 2010-17-18 R1: Eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks at the compliance times specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD, as applicable. Do the inspections following Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002; Snow Engineering Co. Service Letter #245 dated April 25, 2005; Snow Engineering Co. Service Letter #284, dated October 4, 2009.

(i) If the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps have not been cold worked, initially inspect when the airplane reaches a total of 5,500 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 1,100 hours TIS until the 8,000 hours TIS spar replacement time.

(ii) If the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps have been cold worked initially inspect when the airplane reaches a total of 5,500 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later. Repetitively thereafter inspect at intervals not to exceed 2,200 hours TIS until the 8,000 hours TIS spar replacement time.

(3) If no cracks are found during the initial inspections required in paragraphs (i)(1)(i)

and (i)(2)(i) of this AD, to use the longer repetitive inspection intervals specified in paragraphs (i)(1)(ii) and (i)(2)(ii) of this AD, as applicable, you may do the optional cold-working of the lower spar cap fastener holes following Snow Engineering Co. Service Letter #245, dated April 25, 2005.

(4) If any cracks are found during any inspection required in paragraphs (i)(1) and (i)(2) of this AD, before further flight after the inspection where a crack is found, do the actions specified in paragraphs (i)(4)(i) or (i)(4)(ii) of this AD.

(i) For cracks that can be removed by repair, install the 9-bolt splice blocks, cold-work the lower spar cap fastener holes, and eddy current inspect the center splice joint outboard two fastener holes in both the left and right wing main spar lower caps for cracks. This eddy current inspection is required as part of the repair modification and is separate from the inspections required in paragraphs (i)(1) and (i)(2) of this AD. This modification terminates the repetitive inspections required in this AD. Do the repair following Snow Engineering Co. Service Letter #281, dated August 1, 2009; and Snow Engineering Co. Drawing Number 20995, Sheet 3, dated November 25, 2005.

(ii) For cracks that cannot be repaired by doing the actions specified in paragraph (i)(4)(i) of this AD, replace the lower spar caps and associated parts listed following paragraph (i)(5) of this AD, including all subparagraphs.

(5) Replace the wing main spar lower caps, the web plates, the center joint splice blocks and hardware, and the wing attach angles and hardware, and install the steel web splice plate at whichever of the compliance times specified in paragraphs (i)(5)(i), (i)(5)(ii), or (i)(5)(iii) of this AD that occurs first. This replacement terminates the inspections required in this AD, including all subparagraphs. After this replacement the new spar safe life is 11,700 hours TIS. Do the

replacement following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Service Letter #80GG, revised December 21, 2005; Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A, dated January 7, 2009.

(i) *For all airplanes:* Before further flight when cracks are found that cannot be repaired by doing the actions specified in paragraph (i)(4)(i) of this AD.

(ii) *For airplanes previously affected by AD 2010-17-18 R1:* Before or when the airplane reaches the wing main spar lower cap safe life of a total of 8,000 hours TIS or within the next 50 hours TIS after September 9, 2010 (the effective date retained from AD 2010-17-18), whichever occurs later.

(iii) *For airplanes not previously affected by AD 2010-17-18 R1:* Before or when the airplane reaches the wing main spar lower cap safe life of a total of 8,000 hours TIS or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later.

**(j) Actions for Airplanes SNs-0179 Through -0269**

Replace the wing main spar lower caps, the web plates, the center joint splice blocks and hardware, and the wing attach angles and hardware, and install the steel web splice plate at the compliance times specified in paragraphs (j)(1) or (j)(2) of this AD. Do the replacement following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Service Letter #80GG, revised December 21, 2005; and Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A, dated January 7, 2009. After this replacement the new spar safe life is 11,700 hours TIS.

(1) *For airplanes previously affected by AD 2010-17-18 R1:* Unless already done (compliance with AD 2010-17-18 R1), by the 8,000-hour TIS safe life, or within the next 50 hours TIS after September 9, 2010 (the

effective date retained from AD 2010-17-18), whichever occurs later.

(2) *For airplanes not previously affected by AD 2010-17-18 R1:* Unless already done, by the 8,000-hour TIS safe life, or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later.

**(k) Actions for Airplanes S/Ns-0270 and Subsequent Not Affected by AD 2010-17-18 R1**

(1) As of September 29, 2014 (the effective date of this AD), this action establishes the safe life for the wing main spar to be 11,700 hours TIS.

(2) Upon reaching the 11,700-hour TIS safe life or within the next 50 hours TIS after September 29, 2014 (the effective date of this AD), whichever occurs later, replace the wing main spar lower caps, the web plates, the center joint splice blocks and hardware, and the wing attach angles and hardware, and install the steel web splice plate. After this replacement the subsequent new spar safe life is 11,700 hours TIS. Do the replacement following Snow Engineering Co. Service Letter #284, dated October 4, 2009; Snow Engineering Co. Service Letter #80GG, revised December 21, 2005; and Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A, dated January 7, 2009.

**(l) Reporting Requirement for All Airplanes**

Report any crack from any inspection required in paragraphs (g) through (i) of this AD within 30 days after any crack is found using the form in Figure 1 of this AD. Send your report to Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308-3365; fax: (210) 308-3370.

**BILLING CODE 4910-13-P**

**AD 2014-16-17 INSPECTION REPORT**  
**(REPORT ONLY IF CRACKS ARE FOUND)**

**General Information**

1. Inspection Performed By:	2. Phone:
3. Aircraft Model:	4. Aircraft Serial Number:
5. Engine Model Number:	6. Aircraft Total Hours TIS:
7. Wing Total Hours TIS:	8. Lower Spar Cap Hours TIS:

**Previous Inspection/Repair History**

9. Has the lower spar cap been inspected (eddy-current, dye penetrant, magnetic particle, or ultrasound) before? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, an inspection has occurred: Date: _____ Inspection Method: _____ Lower Spar Cap TIS: _____ Cracks found? <input type="checkbox"/> Yes <input type="checkbox"/> No
10. Has there been any major repair or alteration performed to the spar cap? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, specify (Description and hours TIS):

**Inspection for AD 2014-16-17**

11. Date of AD inspection: Inspection Results:	11a. Cracks found: <input type="checkbox"/> Left Hand <input type="checkbox"/> Right Hand
11b. Crack Length: _____ Location: _____	11c. Does drilling hole to next larger size remove all traces of the crack(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No
12d. Corrective Action Taken:	

Send report (only if a cracks is found as a result any inspection required by AD 2014-16-17) to:  
 Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308-3365; fax: (210) 308-3370

Figure 1 to Paragraph (l) of This AD

**BILLING CODE 4910-13-C**

**(m) Special Flight Permit**

Special flight permits are permitted in accordance with 14 CFR 39.23 provided the following limitations are adhered to:

(1) Only operate in day visual flight rules (VFR).

- (2) Ensure that the hopper is empty.
- (3) Limit airspeed to 135 miles per hour (mph) indicated airspeed (IAS).
- (4) Avoid any unnecessary g-forces.
- (5) Avoid areas of turbulence.
- (6) Plan the flight to follow the most direct route.

**(n) Paperwork Reduction Act Burden Statement**

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the

requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

**(o) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Fort Worth Airplane Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (p) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) AMOCs approved for AD 2010-17-18 R1 are approved as AMOCs for this AD.

**(p) Related Information**

For more information about this AD, contact Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308-3365; fax: (210) 308-3370; email: [andrew.mcanaul@faa.gov](mailto:andrew.mcanaul@faa.gov).

**(q) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on September 9, 2010 (75 FR 52255, August 25, 2010).

(i) Snow Engineering Co. Service Letter #80GG, dated December 21, 2005.

(ii) Snow Engineering Co. Service Letter #284, dated October 4, 2009.

(iii) Snow Engineering Co. Service Letter #281, dated August 1, 2009.

(iv) Snow Engineering Co. Service Letter #245, dated April 25, 2005.

(v) Snow Engineering Co. Drawing Number 20995, Sheet 2, Rev. D., dated November 25, 2005.

(vi) Snow Engineering Co. Drawing Number 20995, Sheet 3, dated November 25, 2005.

(vii) Snow Engineering Co. Drawing Number 20975, Sheet 4, Rev. A., dated January 7, 2009

(4) The following service information was approved for IBR on April 21, 2006 (71 FR 19994, April 19, 2006).

(i) Snow Engineering Co. Process Specification #197, page 1, revised June 4, 2002; pages 2 through 4, dated February 23, 2001; and page 5, dated May 3, 2002.

(ii) Snow Engineering Co. Service Letter #240, dated September 30, 2004.

(5) For Air Tractor, Inc. service information identified in this AD, contact Air Tractor, Inc., P.O. Box 485, Olney, Texas 76374; telephone: (940) 564-5616; fax: (940) 564-5612; email: [airmail@airtractor.com](mailto:airmail@airtractor.com); Internet: [www.airtractor.com](http://www.airtractor.com).

(6) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816-329-4148.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on August 7, 2014.

**Earl Lawrence,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014-20098 Filed 8-22-14; 8:45 am]

**BILLING CODE 4910-13-C**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 862**

[Docket No. FDA-2014-N-1112]

**Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of Hemoglobin A1c Test System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying hemoglobin A1c test system into class II (special controls). The special controls that will apply to this device are identified in this order and will be part of the codified language for the hemoglobin A1c test system classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective September 24, 2014. The classification was applicable May 23, 2013.

**FOR FURTHER INFORMATION CONTACT:** Meshawn Payne, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5650, Silver Spring, MD 20993-0002, 301-796-6668.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for