

(1) *For any airplane that has had a wing removed and reinstalled or replaced between June 2007 and July 15, 2016 (the effective date of this AD):* Within the next 12 months after July 15, 2016 (the effective date of this AD), inspect the torlon plates in the forward lower wing-to-fuselage attachments (both left hand (LH) and right hand (RH) sides) for correct installation following the accomplishment instructions in PILATUS AIRCRAFT LTD. PC-12 Service Bulletin No: 57-007, dated September 29, 2015.

(2) *For any airplane that has had a wing removed and reinstalled or replaced, between June 2007 and July 15, 2016 (the effective date of this AD):* If an incorrect installation of the torlon plates is found during the inspection required in paragraph (f)(1) of this AD, remove the affected torlon plates, visually inspect the torlon plates and the affected lugs using a mirror and light source (if necessary) for any damage, and reinstall the torlon plates in the correct sequence, following the accomplishment instructions in paragraph 3.C. of PILATUS AIRCRAFT LTD. PC-12 Service Bulletin No: 57-007, dated September 29, 2015.

(3) *For any airplane that has had a wing removed and reinstalled or replaced, between June 2007 and July 15, 2016 (the effective date of this AD):* If any damage is found during the inspection of the torlon plates and lugs required in paragraph (f)(2) of this AD, before further flight, contact PILATUS AIRCRAFT LTD. for FAA-approved repair instructions and accomplish those instructions accordingly. You may find contact information for PILATUS AIRCRAFT LTD. in paragraph (h) of this AD.

(4) *For all airplanes:* As of July 15, 2016 (the effective date of this AD), do not install or re-install a wing on any airplane, unless concurrent with the wing installation, the torlon plates of the forward lower wing-to-fuselage attachment (both LH and RH sides) of the airplane are inspected and found to be installed correctly in accordance with the accomplishment instructions in paragraph 3.B. of PILATUS AIRCRAFT LTD. PC-12 Service Bulletin No: 57-007, dated September 29, 2015.

**Note 2 to paragraph (f)(4) of this AD:** Installation of a wing on an airplane in accordance with the instructions of PILATUS aircraft maintenance manual (AMM) 02049, Revision 28 or later, or AMM 02300, Revision 11 or later, is an acceptable alternative method to comply with this inspection requirement.

#### (g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; fax: (816) 329-4090; email: [doug.rudolph@faa.gov](mailto:doug.rudolph@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the

FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, 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.

#### (h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2016-0037, dated February 26, 2016, for related information. The MCAI can be found in the AD docket on the Internet at: <https://www.regulations.gov/#/documentDetail;D=FAA-2016-5284-0002>.

#### (i) 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.

(i) PILATUS AIRCRAFT LTD. PC-12 Service Bulletin No: 57-007, dated September 29, 2015.

(ii) Reserved.

(3) For PILATUS AIRCRAFT LTD. service information identified in this AD, contact PILATUS AIRCRAFT LTD., Customer Support Manager, CH-6371 STANS, Switzerland; phone: +41 (0)41 619 33 33; fax: +41 (0)41 619 73 11; email: [SupportPC12@pilatus-aircraft.com](mailto:SupportPC12@pilatus-aircraft.com); Internet: <http://www.pilatus-aircraft.com>.

(4) You may view this 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. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5284.

(5) 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 June 1, 2016.

**Pat Mullen,**

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

[FR Doc. 2016-13372 Filed 6-9-16; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA-2016-4878; Directorate Identifier 2016-CE-001-AD; Amendment 39-18551; AD 2016-12-02]**

**RIN 2120-AA64**

#### **Airworthiness Directives; Various Aircraft Equipped With BRP-Powertrain GmbH & Co KG 912 A Series Engine**

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for various aircraft equipped with a BRP-Powertrain GmbH & Co KG (formerly Rotax Aircraft Engines) 912 A series engine. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as a design change of the engine cylinder head temperature sensor without a concurrent revision of the engine model designation, the engine part number, or the cockpit indication to the pilot. We are issuing this AD to require actions to address the unsafe condition on these products.

**DATES:** This AD is effective July 15, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of July 15, 2016.

**ADDRESSES:** You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-4878; or in person at 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 service information identified in this AD, contact BRP-Powertrain GmbH & Co. KG, Welser Strasse 32, A-4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; Internet: [www.rotax-aircraft-engines.com](http://www.rotax-aircraft-engines.com). You may view this 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. It is also available on the Internet at <http://www.regulations.gov> by searching for Docket No. FAA-2016-4878.

**FOR FURTHER INFORMATION CONTACT:** Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4165; fax: (816) 329-4090; email: [jim.rutherford@faa.gov](mailto:jim.rutherford@faa.gov).

#### SUPPLEMENTARY INFORMATION:

#### Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to various aircraft equipped with a BRP-Powertrain GmbH & Co KG (formerly Rotax Aircraft Engines) 912 A series engine. The NPRM was published in the **Federal Register** on March 28, 2016 (81 FR 17109). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states:

A design change of the engine cylinder heads was introduced by BRP-Powertrain in March 2013 which modifies the engine/aircraft interfaces by substituting the previous cylinder head temperature (CHT) measurement (limit temperature 135 °C/150 °C) with a coolant temperature (CT) measurement (limit temperature 120 °C). The design change was communicated on 15 May 2013 by BRP-Powertrain Service Instruction (SI) 912-020R7/914-022R7 (single document) but was not identified by a change of the engine model designation or of the engine P/N, but only through the cylinder head P/N and the position of the temperature sensor.

Consequently, engines with the new cylinder heads (installed during production or replaced in-service during maintenance) may be installed on an aircraft without concurrent modification of that aircraft, instructions for which should be provided by the Type Certificate (TC) holder or Supplemental Type Certificate (STC) holder, as applicable. In this case, the coolant temperature with a maximum engine operating limit of 120 °C (valid for engines operated with water diluted glycol coolant) is displayed on a CHT indicator with a typical

limit marking (red radial/range) of more than 120 °C.

This condition, if not detected and corrected, will prevent the pilot to identify coolant limit exceedances, with subsequent loss of coolant (120 °C is the boiling temperature of the coolant), which could lead to engine in-flight shut-down, possibly resulting in a forced landing, with consequent damage to the aircraft and injury to occupants.

BRP-Powertrain published revised SI-912-020R8/914-022R8 to clarify that, on the new cylinder heads, the coolant temperature, instead of the cylinder head temperature in the aluminum, is measured. EASA issued SIB 2014-34 to raise awareness that installation of affected engines and spare parts, without concurrent incorporation of aircraft TC/STC holder approved modifications, and even if unintended and unnoticed by production or maintenance, constitutes an unapproved aircraft modification.

Since EASA published the SIB, further investigation has finally determined that sufficient reason exists to warrant AD action.

For the reason stated above, this AD requires a one-time inspection to determine the actual engine configuration and, depending on findings, engine reidentification and (depending on TC or STC holder installation) modification of the affected aircraft. This also affects engines that are operated with waterless coolant.

The MCAI can be found in the AD docket on the Internet at <https://www.regulations.gov/#!documentDetail;D=FAA-2016-4878-0002>.

#### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (81 FR 17109, March 28, 2016) or on the determination of the cost to the public.

#### Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the 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 (81 FR 17109, March 28, 2016) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (81 FR 17109, March 28, 2016).

#### Related Service Information Under 14 CFR Part 51

We reviewed BRP-Powertrain GmbH & CO KG issued Rotax Aircraft Engines BRP Service Bulletin SB-912-068 and SB-914-049 (co-published as one document), dated April 16, 2015. The service information describes procedures for re-identifying the engine

that has new cylinder heads, part numbers 413235 and 413236 installed. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of the AD.

#### Costs of Compliance

We estimate that this AD will affect 65 products of U.S. registry.

We also estimate that it will take about 1 work-hour per product to comply with the engine re-identification requirement of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this portion of this AD on U.S. operators to be \$5,525, or \$85 per product.

We also estimate that it will take about 1 work-hour per product to comply with the engine installation modification to indicate a Maximum Coolant Temperature requirement of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this portion of this AD on U.S. operators to be \$5,525, or \$85 per product.

We also estimate that it will take about 1.5 work-hours per product to comply with the cylinder head replacement option of this AD. The average labor rate is \$85 per work-hour. Required parts will cost about \$2,500 to replace a single engine cylinder head.

Based on these figures, we estimate the cost of this portion of this AD on U.S. operators to be \$2,627.50 per engine cylinder head.

#### 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 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 this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the 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 adding the following new AD:

**2016–12–02 Various Aircraft:** Amendment 39–18551; Docket No. FAA–2016–4878; Directorate Identifier 2016–CE–001–AD.

**(a) Effective Date**

This airworthiness directive (AD) becomes effective July 15, 2016.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all serial numbers of the airplanes listed in table 1 of paragraph (c) of this AD, that are:

- (1) equipped with a BRP-Powertrain GmbH & Co KG (formerly Rotax Aircraft Engines) 912 A series engine with a part number (P/N) 413235 or 413236 cylinder head installed in position 2 or 3; and
- (2) certificated in any category.

TABLE 1 OF PARAGRAPH (C)—AFFECTED AIRPLANES

Type certificate holder	Aircraft model	Engine model
Aeromot-Indústria Mecânico-Metalúrgica Ltda .....	AMT–200 .....	912 A2
Diamond Aircraft Industries .....	HK 36 R “SUPER DIMONA” .....	912 A
DIAMOND AIRCRAFT INDUSTRIES GmbH .....	HK 36 TS and HK 36 TC .....	912 A3
Diamond Aircraft Industries Inc. ....	DA20–A1 .....	912 A3
HOAC-Austria .....	DV 20 KATANA .....	912 A3
Iniziativa Industriali Italiane S.p.A. ....	Sky Arrow 650 TC .....	912 A2
SCHEIBE-Flugzeugbau GmbH .....	SF 25C .....	912 A2, 912 A3

**(d) Subject**

Air Transport Association of America (ATA) Code 72: Engine—Reciprocating.

**(e) Reason**

This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. This AD was prompted by design change of the engine cylinder head temperature sensor without a concurrent revision of the engine model designation, the engine part number, or the cockpit indication to the pilot. The sensor now measures the coolant temperature rather than the cylinder head temperature. If the engine coolant temperature with a maximum engine operating limit of 120 °C is displayed on a Cylinder Head Temperature indicator with a typical limit marking greater than 120 °C, the pilot will be unable to identify coolant temperature limit exceedances. This could result in loss of coolant, which could cause an inflight engine shutdown and forced landing.

**(f) Actions and Compliance**

Unless already done, do the following actions:

- (1) Within 6 months after July 15, 2016 (the effective date of this AD), for engines with cylinder heads listed in paragraph (c)(1) of this AD installed on both position 2 and position 3, change the engine model designation on the engine type data plate to

include a “–01” suffix following paragraph 3.1.1) of the Accomplishment/Instructions in Rotax Aircraft Engines BRP Service Bulletin SB–912–068 and SB–914–049 (co-published as one document), dated April 16, 2015.

(2) Within 6 months after July 15, 2016 (the effective date of this AD), for engines with only one cylinder head listed paragraph (c)(1) of this AD installed in a position 2 or 3, in order to keep such cylinder installed, you must replace the cylinder head installed on the unchanged position (2 or 3, as applicable) with a cylinder head having a P/N listed in paragraph (c)(1) of this AD, and change the engine model designation on the engine type data plate to include a “–01” suffix following paragraph 3.1.1) of the Accomplishment/Instructions in Rotax Aircraft Engines BRP Service Bulletin SB–912–068 and SB–914–049 (co-published as one document), dated April 16, 2015.

(3) Before further flight after doing the required actions in paragraphs (f)(1) or (f)(2) of this AD as applicable, modify the aircraft and related documentation to indicate a Maximum Coolant Temperature limit of 120 °C using FAA-approved procedures.

(i) Such procedures can be found by contacting your aircraft type certificate holder or the FAA contact specified in paragraph (g)(1) of this AD. The service documents referenced in paragraph (h) of this AD are examples of FAA-approved procedures for the applicable aircraft.

(ii) These re-identified engines remain eligible for installation on approved aircraft-engine combinations.

(4) As of July 15, 2016 (the effective date of this AD), do not install any other P/N cylinder head unless that installation is done following approved instructions provided by BRP-Powertrain at the address provided in paragraph (i)(3) of this AD.

**(g) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: [jim.rutherford@faa.gov](mailto:jim.rutherford@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

**(h) Related Information**

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015-0240, dated December 18, 2015; Rotax Aircraft Engines BRP Service Bulletin SB-912-066 R1/SB-914-047 R1 (published as one document), Revision 1, dated April 23, 2015; Diamond Aircraft Industries GmbH Optional Service Bulletin OSB 36-111, dated September 17, 2015; Diamond Aircraft Industries GmbH Work Instruction WI-OSB 36-111, dated September 17, 2015; Diamond Aircraft Service Bulletin No.: DA20-72-04, dated January 22, 2015; Diamond Aircraft Industries GmbH Optional Service Bulletin OSB 20-066, dated September 17, 2015; Diamond Aircraft Industries GmbH Work Instruction WI-OSB 20-066, dated September 17, 2015; and Scheibe Aircraft GmbH Service Information 02/14-1, dated December 15, 2014, for related information. You may examine the MCAI on the Internet at <https://www.regulations.gov/> #!documentDetail;D=FAA-2016-4878-0002. For information on the availability of the service documents above, contact the FAA, Small Airplane Directorate, at 816-329-4148.

**(i) 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.

(i) Rotax Aircraft Engines BRP Service Bulletin SB-912-068 and SB-914-049 (co-published as one document), dated April 16, 2015.

(ii) Reserved.

(3) For BRP-Powertrain GmbH & CO KG service information identified in this AD, contact BRP-Powertrain GmbH & Co. KG, Welser Strasse 32, A-4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; Internet: [www.rotax-aircraft-engines.com](http://www.rotax-aircraft-engines.com).

(4) You may view this 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. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-4878.

(5) 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 June 1, 2016.

**Pat Mullen,**

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

[FR Doc. 2016-13542 Filed 6-9-16; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 886**

[Docket No. FDA-2016-N-1308]

**Medical Devices; Ophthalmic Devices; Classification of Nasolacrimal Compression Device**

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the nasolacrimal compression device into class I (general controls). The Agency is classifying the device into class I (general controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective June 10, 2016. The classification was applicable on April 20, 2016.

**FOR FURTHER INFORMATION CONTACT:** Daniel Fedorko, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2414, Silver Spring, MD 20993-0002, 301-796-6620.

**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 (Pub. L. 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) of the FD&C Act. 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 review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 27, 2014, Innovatex, Inc., submitted a request for classification of the Tear Duct Occluder (originally referred to as the Glaucoma Companion Nasolacrimal Compression Device) under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class I (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class I if general controls by themselves are sufficient to provide reasonable assurance of safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class I. FDA believes general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 20, 2016, FDA issued an order to the requestor classifying the device into class I. FDA