

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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:

**Diamond Aircraft Industries GmbH:** Docket No. FAA-2010-0845; Directorate Identifier 2010-CE-044-AD.

**Comments Due Date**

(a) We must receive comments on this airworthiness directive (AD) action by October 12, 2010.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to Diamond Aircraft Industries GmbH Models DA 40 and DA 40F

airplanes, all serial numbers (S/N), that are certificated in any category.

**Subject**

(d) Air Transport Association of America (ATA) Code 52: Doors.

**Unsafe Condition**

(e) This AD results from several reports of the rear passenger door departing the airplane in flight. We are proposing this AD to change the emergency open doors procedure and retrofit the rear passenger door retaining bracket, which if not corrected could result in the rear passenger door departing the airplane in flight.

**Compliance**

(f) To address this problem, you must do the following, unless already done:

Actions	Compliance	Procedures
(1) <i>For all serial numbers:</i> Incorporate Diamond Aircraft Temporary Revision TR-MAM 40-428, page 3-37b, dated April 30, 2010, into the FAA-approved airplane flight manual.	Within 6 months after the effective date of this AD.	Follow Diamond Aircraft Temporary Revision TR-MAM 40-428, Cover Page, dated April 30, 2010.
(2) <i>For Model DA 40, S/N 40.006 through 40.009, 40.011 through 40.081, 40.084, and 40.201 through 40.749; and Model DA 40F S/N 40.FC001 through 40.FC009:</i> Replace the rear passenger door retaining bracket with an improved design retaining bracket.	Within 6 months after the effective date of this AD.	Follow Diamond Aircraft Industries GmbH Mandatory Service Bulletin NO. MSB 40-070/NO. MSB D4-079/NO. MSB F4-024, dated April 30, 2010; and Diamond Aircraft Industries GmbH Work Instruction WI-MSB 40-070/WI-MSB D4-079/WI-MSB F4-024, dated April 30, 2010.

**Alternative Methods of Compliance (AMOCs)**

(g) The Manager, Small Airplane Directorate, 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: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; e-mail: [mike.kiesov@faa.gov](mailto:mike.kiesov@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.

**Related Information**

(h) To get copies of the service information referenced in this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Strasse 5, A-2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; e-mail: [office@diamond-air.at](mailto:office@diamond-air.at); Internet: <http://www.diamond-air.at>. To view the AD docket, go to U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or on the Internet at <http://www.regulations.gov>.

Issued in Kansas City, Missouri, on August 18, 2010.

**John R. Colomy,**

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

[FR Doc. 2010-21068 Filed 8-24-10; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 870, 884 and 892**

**[Docket No. FDA-2010-N-0412]**

**RIN 0910-AG51**

**Effective Date of Requirement for Premarket Approval for Four Class III Preamendments Devices**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following four class III preamendments devices: Ventricular bypass (assist) device; pacemaker repair or replacement

material; female condom; and transilluminator for breast evaluation. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of any of the aforementioned devices based on new information. This action implements certain statutory requirements.

**DATES:** Submit written or electronic comments by November 23, 2010. Submit requests for a change in classification by September 9, 2010. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XIII of this document for the effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2010-N-0412 and/or RIN number 0910-AG51, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

• Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and Docket Number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Michael Ryan, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993, 301–796–6283.

#### SUPPLEMENTARY INFORMATION:

##### I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), the Medical Devices Technical Corrections Act (Public Law 108–214), and the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed

to provide reasonable assurance of their safety and effectiveness. The three categories of devices are: Class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is 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 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 act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA promulgates a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE)

(see 21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The regulation; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 180 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. Section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease since the device would

be deemed adulterated under section 501(f) of the act.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and the device does not comply with IDE regulations, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA or PDP has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that: [t]he thirty month grace period afforded after classification of a device into class III \* \* \* is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval (H. Rept. 94-853, 94th Cong., 2d sess. 42 (1976)).

The SMDA added section 515(i) to the act requiring FDA to review the classification of preamendments class III devices for which no final rule requiring the submission of PMAs has been issued, and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, the SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Proceeding directly to rulemaking under section 515(b) of the act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMAs have not been previously required either be reclassified to class I or class II or be subject to the requirements of premarket approval.

Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

## II. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the act, the agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that "the continued availability of the device is necessary for the public health."

FDA intends that under § 812.2(d) (21 CFR 812.2(d)), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions from the requirements of the IDE regulations for preamendments class III devices in § 812.2(c)(1) and (c)(2) will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under 21 CFR 812.30. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the

issuance of the final rule to avoid interrupting investigations.

## III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with information submitted in response to the 515(i) order (74 FR 16214, April 9, 2009) and any additional information that FDA has encountered. Additional information regarding the risks as well as classification associated with these device types can be found in the following proposed and final rules published in the **Federal Register** on these dates: Cardiovascular devices, 21 CFR part 870 (44 FR 13284, March 9, 1979; 45 FR 7904, February 5, 1980; and 52 FR 17736, May 11, 1987); classification of female condoms (64 FR 31164, June 10, 1999; and 65 FR 31454, May 18, 2000); and classification of transilluminators (diaphanosopes or lightscanners) for breast evaluation (60 FR 3168, January 13, 1995; and 60 FR 36639, July 18, 1995).

## IV. Devices Subject to This Proposal

### A. Ventricular bypass (assist) device (21 CFR 870.3545)

#### 1. Identification

A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.

#### 2. Summary of Data

The Cardiovascular Devices Panel recommended that ventricular bypass (assist) devices be classified into class III because the device is an implant used in a life-supporting situation. The panel indicated that general controls alone would not be sufficient and that there was not enough information to establish a performance standard. Consequently, the panel believed that premarket approval is necessary to assure the safety and effectiveness of the device. FDA continues to agree with the panel's recommendation.

#### 3. Risks to Health

a. *Thromboembolism*—inadequate blood compatibility of the materials

used in this device and inadequate surface finish and cleanliness could lead to potentially debilitating or fatal thromboembolism.

b. *Excessive hemolysis*—poor design of the hemodynamic characteristics of the device can lead to excess hemolysis.

c. *Inability to support life*—inaccurate pressure or flow control or improper synchronization can impede the ability of the device to support life.

d. *Cardiac arrhythmias or electrical shock*—excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage can also cause electrical shock to the physician during placement or use of the device and this could lead to iatrogenic complications.

e. *Interference with other organs*—because of the device's size and the location of its implantation, the device may interfere with the function of other organs.

f. *Damage to blood vessels*—the mechanical design of the attachments is associated with the possibility of damage to blood vessels at the attachment points.

g. *Inability to maintain long-term support*—low fatigue life of the materials used or poor quality control in construction can lead to premature breakdown of the device.

#### B. *Pacemaker repair or replacement material (21 CFR 870.3710)*

##### 1. Identification

A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

##### 2. Summary of Data

The Cardiovascular Devices Classification Panel recommended that pacemaker repair or replacement material be classified into class III because of the potential hazards associated with the inherent properties of the device, the life-supporting function of this implanted device, and its personal knowledge of, and experience with, the device. FDA agreed and continues to agree with the panel's recommendation. The agency notes that the device has fallen into disuse and that the published data are not adequate to demonstrate the safety and effectiveness of the device.

##### 3. Risks to Health

a. *Tissue damage*—If the biocompatibility of the materials used in this device is inadequate, damage to the surrounding tissue may result.

b. *Loss of pacing function*—Failure to properly repair or reconnect a pacemaker lead could result in loss of pacing function. The need to repair/reconnect the lead may be due to, among other causes, an intrusion of fluid into the pacemaker connection, an improper electrical connection to the pacemaker circuitry, or poor electrical insulation of the lead body. If the lead is not repaired or reconnected, the electrical path from the pulse generator to the lead may be interrupted, resulting in a loss of critical and potentially life-sustaining pacing function.

#### C. *Female condom (21 CFR 884.5330)*

##### 1. Identification

A female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for contraceptive and prophylactic (preventing the transmission of sexually transmitted diseases (STDs)) purposes.

##### 2. Summary of Data

The Obstetrics-Gynecology Devices Panel recommended that the female condom device be classified into Class III (premarket approval). The panel gave reasons for recommendation, e.g., that no published data could be found that demonstrate the safety and effectiveness of the device. The panel based the recommendation on information provided by FDA and on the panel members' personal knowledge of and experience with contraceptive methods of birth control, including barrier-type contraceptives. Additionally, the panel believed that general controls and special controls would not provide reasonable assurance of the safety and effectiveness of the devices. FDA has not received any new data to affect the classification. FDA agreed and continues to agree with the panel's recommendation. The agency notes that the device has fallen into disuse and that the published data are not adequate to demonstrate the safety and effectiveness of the device.

##### 3. Risks to Health

a. *Pregnancy*—Leakage, breakage, dislodgement, or displacement of the device during sexual intercourse could result in the occurrence of an undesired pregnancy.

b. *Transmission of infection (disease)*—If the device fails due to leakage, breakage, dislodgement, or displacement, contact with infected semen or vaginal secretions or mucosa could result in the transmission of STD's, including human immunodeficiency virus (HIV) (causing

acquired immunodeficiency syndrome (AIDS)).

c. *Adverse tissue reaction*—Unless the biocompatibility of materials and substances compromising the device are tested, local tissue irritation and sensitization or systemic toxicity could occur when the vaginal pouch contacts the vaginal wall, cervical mucosa, and the penis.

d. *Ulceration and other physical trauma*—Depending on the design of the device, use of the female condom may cause abrasions, lacerations, bleeding, or other adverse effects to the vaginal or penile tissue.

#### D. *Transilluminator for breast evaluation (21 CFR 892.1990)*

##### 1. Identification

A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700 to 1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

##### 2. Summary of Data

The Obstetrics and Gynecology Devices Panel recommended that transilluminator devices for breast evaluation be classified into class III and subject to premarket approval to provide reasonable assurance of the safety and effectiveness of the device. The panel concluded that there were no published studies or clinical data demonstrating the safety and effectiveness of the device. The panel indicated that the device presents a potential unreasonable risk of illness or injury to the patient if the clinician relies on the device and that although the device's illumination level, wavelength, and image quality can be controlled through tests and specifications, insufficient evidence exists to determine that special controls can be established to provide reasonable assurance of the safety and effectiveness of the device for its intended use. FDA has not received any new data to affect the classification. FDA agreed and continues to agree with the panel's recommendation. The agency notes that the device has fallen into disuse and that the published data are not adequate to demonstrate the safety and effectiveness of the device.

##### 3. Risks to Health

a. *Missed or delayed diagnosis*—As a result of the questionable device performance of breast transilluminators, missed or delayed diagnosis are the

most catastrophic risks to health for a woman. These devices depend on the users' visual interpretation of their own breast illumination. One scenario may result when a woman incorrectly interprets her transillumination as a tumor and suffers the ensuing anxiety from her belief that she has a cancer. Another scenario may result when a woman incorrectly dismisses the findings of her transillumination and then suffers from a missed diagnosis or delayed diagnosis and delayed treatment. Ultimately, missed or delayed diagnoses could result in the need for more aggressive treatment and a potentially higher risk of death.

b. *Electrical shock*—If a breast transilluminator is not designed properly, the user may receive an electrical shock.

c. *Optical radiation*—Prolonged gazing directly into the light of a breast illuminator while engaged in "bright light mode" may result in retinal damage.

#### V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 CFR 860.7(c)(2)). Valid scientific evidence is "evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

\* \* \* Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to

show safety or effectiveness." (21 CFR 860.7(c)(2)).

#### VI. PDP Requirements

A PDP for any of these devices may be submitted instead of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP must provide: (1) A description of the device, (2) preclinical trial information (if any), (3) clinical trial information (if any), (4) a description of the manufacturing and processing of the devices, (5) the labeling of the device, and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

#### VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### VIII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of these devices is to be in the form of a reclassification petition containing the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

The agency advises that to ensure timely filing of any such petition, any request should be submitted to the Division of Dockets Management (see **ADDRESSES**) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of these devices is submitted, the agency will, within 180 days after receipt of the petition, and after consultation with the appropriate FDA resources, publish an order in the **Federal Register** that either

denies the request or gives notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

#### IX. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because there have been no premarket submissions for these devices in the past 5 years and all of the affected devices have fallen into disuse, FDA has concluded that there is little or no interest in marketing these devices in the future. Therefore, the agency proposes to certify that the proposed rule, if issued as a final rule, would not have a significant economic impact on a substantial number of small entities. We specifically request detailed comment regarding the appropriateness of our assumptions regarding the potential economic impact of this proposed rule.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$135

million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA proposes to certify that this proposed rule, if issued as a final rule, would not have a significant economic impact. We base this determination on an analysis of registration and listing and other data for the affected devices. Two of the devices affected by this proposed rule, the female condom and ventricular bypass device, have never appeared in FDA's electronic

registration and listing database. These devices were identified as preamendment devices, but since their classification, the agency has no record of them ever being marketed. In addition, these devices represent older technologies that have since been replaced by newer technologies, currently being marketed under a Premarket Approval Application, or PMA.

One of the affected devices, pacemaker repair and replacement material, is a material that can be used in multiple devices that was last listed in 2001 and the agency is aware of no

evidence that the device has been marketed since 1991. In addition, on the increasingly rare occasions when a pacemaker is repaired today, the repair is done with materials specific to the approved device. The final affected device, the breast transilluminator, was last listed in 2007 but FDA has never cleared a 510(k) for this type of device. Although this device was listed as recently as 2007, the device was never approved or cleared for marketing. This information is summarized in table 1 of this document as follows:

TABLE 1.—SUMMARY OF ELECTRONIC REGISTRATION AND LISTING INFORMATION

Device Name	Product Code	510(k) or PMA?	Last Listed	Last Marketed	Replaced by Approved Technology?
Female Condom	OBY	No	Never Listed	1930s	Yes
Ventricular Bypass Device	OKR	No	Never Listed	No Record	Yes
Pacemaker Repair and Replacement	KFJ	No	2001	1991	Yes
Breast Transilluminator	LEK	No	2007	No Record	No

Based on our review of electronic product registration and listing and other data, FDA concludes that there is currently little or no interest in marketing the affected devices and that the proposed rule would not have a significant economic impact. We specifically request detailed comment regarding the appropriateness of our assumptions regarding the potential economic impact of this proposed rule.

#### XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects 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. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### XII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 814, subpart B have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR 801 have been approved under OMB control number 0910–0485.

#### XIII. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 12 months after the date of its publication in the **Federal Register** or at a later date if stated in the final rule.

#### List of Subjects 21 CFR Parts 870, 884, and 892

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 870, 884, and 892 be amended as follows:

#### PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.3545 is amended by revising paragraph (c) to read as follows:

#### § 870.3545 Ventricular bypass (assist) device.

\* \* \* \* \*

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [date 90 days after date of publication of the final rule in the **Federal Register**], for any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976. Any other ventricular bypass (assist) device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

3. Section 870.3710 is amended by revising paragraph (c) to read as follows:

#### § 870.3710 Pacemaker repair or replacement material.

\* \* \* \* \*

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [date 90 days after date of publication of the

*final rule in the Federal Register*], for any pacemaker repair or replacement material device that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the Federal Register], been found to be substantially equivalent to any pacemaker repair or replacement material device that was in commercial distribution before May 28, 1976. Any other pacemaker repair or replacement material device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

#### PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

4. The authority citation for 21 CFR part 884 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 884.5330 is amended by revising paragraph (c) to read as follows:

##### § 884.5330 Female condom.

\* \* \* \* \*

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [date 90 days after date of publication of the final rule in the Federal Register], for any female condom that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the Federal Register], been found to be substantially equivalent to any female condom that was in commercial distribution before May 28, 1976. Any other female condom shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

#### PART 892—RADIOLOGY DEVICES

6. The authority citation for 21 CFR part 892 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

7. Section 892.1990 is amended by revising paragraph (c) to read as follows:

##### § 892.1990 Transilluminator for breast evaluation.

\* \* \* \* \*

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before [date 90 days after date of publication of the final rule in the Federal Register], for any transilluminator for breast evaluation that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date

*of publication of the final rule in the Federal Register*], been found to be substantially equivalent to any transilluminator for breast evaluation that was in commercial distribution before May 28, 1976. Any other transilluminator for breast evaluation shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 19, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010–21142 Filed 8–24–10; 8:45 am]

BILLING CODE 4160–01–S

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 253

[Docket No. 0908061221–91225–01]

RIN 0648–AY16

##### Merchant Marine Act and Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fishing Vessel, Fishing Facility and Individual Fishing Quota Lending Program Regulations; Correction

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule, correction and reopening of comment period.

**SUMMARY:** NMFS published a proposed rule on May 5, 2010, amending the Fisheries Finance Program's programmatic regulations. The proposed rule was published with an incorrect Regulatory Identification Number (RIN) in the ADDRESSES section. Members of the public using the incorrect RIN may have had difficulty posting comments at <http://www.regulations.gov>. In order to allow anyone adversely affected by the mistake to submit comments, NMFS reopens the comment period and requests additional comments for two weeks.

**DATES:** NMFS invites the public to comment on the proposed rule published at 75 FR 24549. Comments must be submitted in writing on or before September 8, 2010.

**ADDRESSES:** You may submit comments on the proposed rule, identified by RIN 0648–AY16 by any one of the following methods:

- **Electronic Submissions:** Submit all electronic public comments via the Federal eRulemaking Portal at <http://www.regulations.gov>.

- **Fax:** (301) 713–1306, Attn: Earl Bennett.

- **Mail:** Earl Bennett, Acting Chief, Financial Services Division, NMFS, Attn: F/MB5, 1315 East-West Highway, SSMC3, Silver Spring, MD 20910.

**Instructions:** All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only. Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to [earl.bennett@noaa.gov](mailto:earl.bennett@noaa.gov) or [david.rostker@omb.eop.gov](mailto:david.rostker@omb.eop.gov) or faxed to (202) 395–7285.

**FOR FURTHER INFORMATION CONTACT:** Earl Bennett, (301) 713–2390 x 187, [earl.bennett@noaa.gov](mailto:earl.bennett@noaa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Need for Correction

On May 5, 2010, NMFS published a proposed rule at 75 FR 24549, which can be viewed at <http://www.fakr.noaa.gov/prules/75fr24549.pdf>.

The ADDRESSES section of the proposed rule contained an incorrect RIN. Although members of the public submitting comments by mail, fax and e-mail to the addresses listed in the proposed rule would have been unaffected, those attempting to post comments at <http://www.regulations.gov> may have been hindered from posting comments because of this error. In order to allow anyone adversely affected by the mistake the opportunity to comment, NMFS will take comments for an additional two weeks.

The new sentence in the ADDRESSES section of column one in 75 FR 24550 should read: "You may submit comments, identified by 0648–AY16, by any one of the following methods:"