20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Electronic copies are available on the Commission's Web site. The address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml*. You can also inspect the document 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/code_of_federal_regulations/ibr_locations.html.*

Dated: March 4, 2014.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2014–05057 Filed 3–7–14; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2014–N–0107]

Medical Devices; General and Plastic Surgery Devices; Classification of the Absorbable Lung Biopsy Plug

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the absorbable lung biopsy plug into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the absorbable lung biopsy plug's 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 April 9, 2014. The classification was effective on December 19, 2012.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2532, Silver Spring, MD 20993–0002, 301–796–6274.

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), 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, July 9, 2012, 126 Stat. 1054), 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) 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), 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) 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). 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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on March 19, 2009, classifying the Bio-Seal Lung Biopsy Tract Plug System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On April 16, 2009, Angiotech submitted a request for classification of the Bio-Seal Lung Biopsy Tract Plug System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (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 II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2012, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4755.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an absorbable lung biopsy plug will need to comply with the special controls named in this final order.

The device is assigned the generic name Absorbable Lung Biopsy Plug, and it is identified as a preformed (polymerized) absorbable lung biopsy plug intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures.

Identified potential risk	Recommended mitigation measure
Inability to deploy plug	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Delayed plug expansion	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Leakage around plug	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Plug migration (whole plug and/or fragments)	Design and Material Characterization Bench Testing In Vivo Evaluation Labeling
Procedural complications	In Vivo Evaluation Labeling
Adverse tissue reaction	Biocompatibility In Vivo Evaluation
Infection	Biocompatibility Sterility Shelf-Life Testing
Use error	Labeling

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.

(3) In vivo evaluation must demonstrate performance characteristics of the device including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

(4) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

(5) Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

(6) The device must be demonstrated to be biocompatible.

(7) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labeling must include identification of compatible introducer needles.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the absorbable lung biopsy plug they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. Request from Angiotech, dated April 16, 2009.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4755 is added to subpart E to read as follows:

§ 878.4755 Absorbable Lung Biopsy Plug.

(a) *Identification.* A preformed (polymerized) absorbable lung biopsy plug is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract,

the plug expands to fill the biopsy void and remains in place until resorbed.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.

(3) In vivo evaluation must demonstrate performance characteristics of the device, including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

(4) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

(5) Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

(6) The device must be demonstrated to be biocompatible.

(7) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labeling must include identification of compatible introducer needles.

Dated: February 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05061 Filed 3–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301, and 602

[TD 9660]

RIN 1545–BL31

Information Reporting of Minimum Essential Coverage

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations providing guidance to providers of minimum essential health coverage that are subject to the information reporting requirements of section 6055 of the Internal Revenue Code (Code), enacted by the Patient Protection and Affordable Care Act. Health insurance issuers, certain employers, and others that provide minimum essential coverage to individuals must report to the IRS information about the type and period of coverage and furnish the information in statements to covered individuals. These final regulations affect health insurance issuers and carriers, employers, governments, and other persons that provide minimum essential coverage to individuals.

DATES: *Effective Date:* These regulations are effective on March 10, 2014.

Applicability Dates: For dates of applicability, see §§ 1.6055–1(j) and 1.6055–2(b).

FOR FURTHER INFORMATION CONTACT: Andrew Braden, (202) 317–4718 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–2252.

The collection of information in these final regulations is in §§ 1.6055–1 and 1.6055–2. The collection of information will be used to determine whether an individual has minimum essential coverage under section 1501(b) of the Patient Protection and Affordable Care Act (26 U.S.C. 5000A(f)). The collection of information is required to comply with the provisions of sections 5000A and 6055 of the Code. The likely respondents are health insurance issuers and carriers, self-insured employers or other sponsors of self-insured group health plans, and governments that provide minimum essential coverage.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

The burden for the collection of information contained in these final regulations will be reflected in the burden on Form 1095–B or another form that the IRS designates, which will request the information in the final regulations.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by section 6103.

Background

This document contains final regulations that amend the Income Tax Regulations (26 CFR part 1) under sections 6055 and 6081 and the Procedure and Administration Regulations (26 CFR part 301) under sections 6011, 6721, and 6722, relating to the requirement for providers of minimum essential coverage (as defined in section 5000A(f)) to report to the IRS certain information about individuals covered by minimum essential coverage and to provide a statement to the individuals. Section 6055 was enacted by section 1502 of the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)), which together with the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)), is referred to as the Affordable Care Act.

On September 9, 2013, a notice of proposed rulemaking (REG–132455–11) was published in the **Federal Register** (78 FR 54986). Written comments responding to the proposed regulations were received. A public hearing was held on November 19, 2013. The comments are available for public inspection at *www.regulations.gov* or on request. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision. These final regulations also include certain nonsubstantive revisions to increase consistency with final regulations issued under section 6056 (TD 9661) contemporaneously with these regulations

Explanation of Provisions and Summary of Comments

1. Coverage Subject To Reporting

a. Minimum Essential Coverage

The proposed regulations provided that every person that provides minimum essential coverage to an individual during a calendar year must file an information return and a transmittal on forms prescribed by the IRS. Minimum essential coverage is defined in section 5000A(f) and regulations issued under that section.

Commenters suggested that section 6055 reporting should not be required for an individual who may be exempt from the individual shared responsibility payment under section 5000A.

Providers of minimum essential coverage, including employers providing coverage under a self-insured group health plan, may not have the information necessary to determine an individual's exempt status under