databases. As such, these special conditions address these vulnerabilities.

The digital systems architecture for the Boeing Model 767–2C series airplanes is composed of several connected networks. This network architecture is used for a diverse set of functions providing data connectivity between systems, including:

1. Airplane control, communication, display, monitoring and navigation systems,

2. operator business and administrative support systems,

3. passenger entertainment systems, and

4. access by systems external to the airplane.

The Model 767–2C series airplane electronic-system network architecture allows connection to airplane electronic systems and networks, and access from airplane external sources (*e.g.,* operator networks, wireless devices, Internet connectivity, service-provider satellite communications, electronic flight bags, etc.) to the previously isolated airplane electronic assets.

This design may result in network-security vulnerabilities from intentional or unintentional corruption of data and systems required for the safety, operations, and maintenance of the airplane. The existing regulations and guidance material did not anticipate this type of system architecture, or external wired and wireless electronic access to airplane electronic systems. Furthermore, regulations, and current system safety-assessment policy and techniques, do not address potential security vulnerabilities, which could be caused by unauthorized access to airplane electronic systems and networks.

Special conditions have been applied on past airplane programs to require consideration of related security vulnerabilities. These special conditions are similar to those previously applied, except that the scope has been adjusted to be consistent with those features unique to the Model 767–2C series airplane.

Applicability

As discussed above, these special conditions apply to Boeing Model 767–2C series airplanes. Should Boeing apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances, and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**.

The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Boeing Model 767–2C series airplanes.

1. The applicant must ensure airplane electronic-system security protection from access by unauthorized sources external to the airplane, including those possibly caused by maintenance activity.

2. The applicant must ensure that electronic-system security threats are identified and assessed, and that effective electronic-system security protection strategies are implemented to protect the airplane from all adverse impacts on safety, functionality, and continued airworthiness.

3. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Renton, Washington, on February 19, 2015.

John J. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–03970 Filed 2–25–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2014–M–1957]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Assisted Reproduction Embryo Image Assessment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Assisted Reproduction Embryo Image Assessment System 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 Assisted Reproduction Embryo Image Assessment System classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective February 26, 2015. The classification was applicable June 6, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Bailey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G120, Silver Spring, MD 20993–0002, 301–796–6530.

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), 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), the person requests a classification under section 513(f)(2) of the FD&C Act. 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 August 3, 2012, FDA issued an order classifying the EEVA 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 August 23, 2012, Auxogyn, Inc., submitted a de novo request for classification of the EEVA 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, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 6, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 884.6195 (21 CFR 884.6195).

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for an Assisted Reproduction Embryo Image Assessment System will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name Assisted Reproduction Embryo Image Assessment System, and it is identified as a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in Table 1:

TABLE 1—ASSISTED REPRODUCTION EMBRYO IMAGE ASSESSMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Damage or Destruction of the Embryo	Non-Clinical Performance Testing. Software Verification, Validation & Hazard Analysis. Clinical Testing. Electromagnetic Compatibility Testing. Electrical Safety Testing. Labeling. Training.
Infection (Contamination of Device, Labware, and Incubator)	Cleaning and Disinfection Validation. Labeling. Training.
Incorrect Embryo Development Prediction	Non-Clinical Performance Testing. Software Verification, Validation & Hazard Analysis. Clinical Testing. Labeling. Training.
Electromagnetic Interference/Electrical Safety Issues	Electromagnetic Compatibility Testing. Electrical Safety Testing. Labeling.
Use Error	Labeling. Training.

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

- Clinical performance testing must demonstrate a reasonable assurance of the safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be

assessed at the subject and embryo levels.
- Software validation, verification, and hazard analysis must be provided.
- Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:
  - Total light exposure and output testing;
  - a safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device;
  - simulated-use testing;
  - Mouse Embryo Assay testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage;
  - cleaning and disinfection validation of reusable components;
  - package integrity and transit testing;
  - hardware fail-safe validation;
  - electrical equipment safety and electromagnetic compatibility testing; and
  - prediction algorithm reproducibility.
- Labeling must include the following:
  - A detailed summary of clinical performance testing, including any adverse events;
  - specific instructions, warnings, precautions, and training needed for safe use of the device;
  - appropriate electromagnetic compatibility information;
  - validated methods and instructions for cleaning and disinfection of reusable components; and
  - information identifying compatible cultureware and explain how they are used with the device.

An Assisted Reproduction Embryo Image Assessment System is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (See 21 CFR 801.109 (*Prescription devices*).)

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 Assisted Reproduction Embryo Image Assessment System 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 administrative 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.

1. K120427: De Novo Request from Auxogyn, Inc., dated August 23, 2012.

List of Subjects in 21 CFR Part 884

Medical devices, Obstetrical and Gynecological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

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

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

■ 2. Section 884.6195 is added to subpart G to read as follows:

§ 884.6195 Assisted Reproduction Embryo Image Assessment System.

(a) *Identification.* An Assisted Reproduction Embryo Image Assessment System is a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.

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

(1) Clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be assessed at the subject and embryo levels.

(2) Software validation, verification, and hazard analysis must be provided.

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Total light exposure and output testing;

(ii) A safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device;

(iii) Simulated-use testing;

(iv) Mouse Embryo Assay testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage;

(v) Cleaning and disinfection validation of reusable components;

(vi) Package integrity and transit testing;

(vii) Hardware fail-safe validation;

(viii) Electrical equipment safety and electromagnetic compatibility testing; and

(ix) Prediction algorithm reproducibility.

(4) Labeling must include the following:

(i) A detailed summary of clinical performance testing, including any adverse events;

(ii) Specific instructions, warnings, precautions, and training needed for safe use of the device

(iii) Appropriate electromagnetic compatibility information;

(iv) Validated methods and instructions for cleaning and disinfection of reusable components; and

(v) Information identifying compatible cultureware and explain how they are used with the device.

Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03934 Filed 2–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 57

[TD 9711]

RIN 1545–BM52

Health Insurance Providers Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations that provide rules for the definition of a covered entity for purposes of the fee imposed by section 9010 of the Patient Protection and Affordable Care Act, as amended. The temporary regulations are necessary to clarify certain terms in section 9010. The temporary regulations affect persons engaged in the business of providing health insurance for United States health risks. The text of the temporary regulations also serves as the text of the proposed regulations (REG–143416–14) published in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on February 26, 2015.

Applicability Date: For dates of applicability, see §§ 57.10 and 57.10T.

FOR FURTHER INFORMATION CONTACT: Rachel S. Smith, (202) 317–6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 9010 of the Patient Protection and Affordable Care Act (PPACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 10905 of PPACA, and as further amended by section 1406 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)) (collectively, the Affordable Care Act or ACA) imposes an annual fee on covered entities that provide health insurance for United States health risks. All references in this preamble to section 9010 are references to the ACA. Section 9010 did not amend the Internal Revenue Code (Code) but contains cross-references to specified Code sections. Unless otherwise indicated, all other references to subtitles, chapters, subchapters, and sections in this preamble are references to subtitles, chapters, subchapters, and sections in the Code and related regulations. All references to ''fee'' in this preamble are references to the fee imposed by section 9010.

On November 27, 2013, the Treasury Department and the IRS issued the Health Insurance Providers Fee regulations as final regulations (TD 9643). On August 12, 2014, the Treasury Department and the IRS issued Notice 2014–47, 2014–35 IRB 522, to provide further guidance for the 2014 fee year on the definition of a covered entity. The temporary regulations provide further guidance on the definition of a covered entity for the 2015 fee year and subsequent fee years.

General Overview

Section 9010(a) imposes an annual fee on each covered entity engaged in the business of providing health insurance. The fee is due by the annual date specified by the Secretary, but in no event later than September 30th of each calendar year in which a fee must be paid (fee year).

Section 9010(b) requires the Secretary to determine the annual fee for each covered entity based on the ratio of the covered entity's net premiums written for health insurance for any United States health risk that are taken into account for the calendar year immediately before the fee year (data year) to the aggregate net premiums written for health insurance of United States health risks of all covered entities that are taken into account during the data year. In calculating the fee, the Secretary must determine each covered entity's net premiums written for United States health risks based on reports submitted to the Secretary by the covered entity and through the use of any other source of information available to the Secretary.

Section 9010(c)(1) defines a covered entity as any entity that provides health insurance for any United States health risk during each fee year. Section 9010(c)(2) excludes the following entities from being covered entities: (A) Any employer to the extent that the employer self-insures its employees' health risks; (B) any governmental entity; (C) any entity (i) that is incorporated as a nonprofit corporation under a State law, (ii) no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation (except as otherwise provided in section 501(h)), and which does not participate in, or intervene in, any political campaign on behalf of (or in opposition to) any candidate for public office, and (iii) more than 80 percent of the gross revenues of which is received from government programs that target low income, elderly, or disabled populations under titles XVIII, XIX, and XXI of the Social Security Act; and (D) any entity that is described in section 501(c)(9) (a voluntary employees' beneficiary association (VEBA)) and is established by an entity (other than by an employer or employers) for purposes of providing health care benefits.

Section 9010(c)(3)(A) provides a controlled group rule under which all persons treated as a single employer under section 52(a) or (b) or section 414(m) or (o) are treated as a single covered entity. Section 9010(c)(4) provides that, if more than one person is liable to pay the fee on a single covered entity by reason of the application of the controlled group rule, then all such persons are jointly and severally liable for payment of the fee.

Section 57.2(c)(1) of the Health Insurance Providers Fee regulations defines the term *controlled group* to mean a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o). Section 57.2(c)(3)(ii) further provides that a person is treated as being a member of the controlled group if it is a member of the group at the end of the day on December 31st of the data year.

Explanation of Provisions

Following the publication of the final regulations in TD 9643, the Treasury Department and the IRS received questions about how to apply the exclusions under section 9010(c)(2) to the general definition of a covered entity. The Treasury Department and the IRS also received questions about whether covered entities must report information on net premiums written for certain members of a controlled group. Notice 2014–47 was subsequently issued to resolve those questions for the 2014 fee year. The temporary regulations adopt the general approach of Notice 2014–47 to resolve those questions for the 2015 fee year and each subsequent fee year.

Application of Exclusions Under Section 9010(c)(2)

Notice 2014–47 provided that, for the 2014 fee year, the Treasury Department and the IRS would not treat any entity as a covered entity if it would be