These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions apply to Gulfstream Model GVII–G500 airplanes. Should Gulfstream apply later for a change to the type certificate to include another model incorporating the same or similar novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Gulfstream Model GVII–G500 airplanes. It is not a rule of general applicability.

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 Gulfstream Model GVII–G500 airplanes.

In addition to the requirements of §§ 25.143, 25.671, 25.672, and 25.1322, when a flight condition exists where, without being commanded by the crew, control surfaces are coming so close to their limits that return to the normal flight envelope, or continuation of safe flight, or both, requires a specific crew action, a suitable flight-control-position annunciation must be provided to the crew, unless other existing indications are found adequate or sufficient to prompt that action.

Note: The term ''suitable'' indicates an appropriate balance between necessary operation and nuisance factors.

Issued in Renton, Washington, on August 7, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–20296 Filed 8–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2015–N–2723]

Medical Devices; Cardiovascular Devices; Classification of the Esophageal Thermal Regulation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the esophageal thermal regulation device 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 esophageal thermal regulation device'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 August 18, 2015. The classification was applicable on June 23, 2015.

FOR FURTHER INFORMATION CONTACT: Lydia Glaw, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1102, Silver Spring, MD 20993–0002, 301–796–1456, *Lydia.glaw@fda.hhs.gov.*

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). 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 May 8, 2014, Advanced Cooling Therapy, LLC, submitted a request for classification of the Esophageal Cooling Device 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). 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 could 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 23, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 870.5910.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an esophageal thermal regulation device will need to comply with the special controls named in this final order. The device is assigned the generic name esophageal thermal regulation device, and it is identified as a prescription device used to apply a specified temperature to the endoluminal surface of the esophagus via an external controller. This device may incorporate a mechanism for gastric decompression and suctioning. The device is used to regulate patient temperature.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

TABLE 1—ESOPHAGEAL THERMAL REGULATION DEVICE RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction.	Biocompatibility testing.
Gastric distension.	Non-clinical performance evaluation. Labeling.
Injury to the esophagus.	Non-clinical performance evaluation. Animal testing. Labeling.
Harmful hypo/hyperthermia.	Non-clinical performance evaluation. Animal testing. Labeling.
Injury to the trachea.	Labeling.

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

- The patient contacting materials must be demonstrated to be biocompatible.
- Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
  - Mechanical integrity testing;
  - Testing to determine temperature change rate(s);
  - Testing to demonstrate compatibility with the indicated external controller; and
  - Shelf life testing.
- Animal testing must demonstrate that the device does not cause esophageal injury and that body temperature remains within appropriate boundaries under anticipated conditions of use.
- Labeling must include the following:
  - Detailed insertion instructions;
  - Warning against attaching the device to unintended connections, such as external controllers for which the device is not indicated, or pressurized air outlets instead of vacuum outlets for those devices, including gastric suction;
  - The operating parameters, name, and model number of the indicated external controller; and
  - The intended duration of use.

Esophageal thermal regulation devices are prescription devices 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), 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 esophageal thermal regulation device 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. DEN140018: De Novo Request per 513(f)(2) from Advanced Cooling Therapy, LLC, dated May 8, 2014.

List of Subjects in 21 CFR Part 870

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 870 is 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. Add § 870.5910 to subpart F to read as follows:

§ 870.5910 Esophageal thermal regulation device.

(a) *Identification.* An esophageal thermal regulation device is a prescription device used to apply a specified temperature to the endoluminal surface of the esophagus via an external controller. This device may incorporate a mechanism for gastric decompression and suctioning. The device is used to regulate patient temperature.

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

(1) The patient contacting materials must be demonstrated to be biocompatible.

(2) Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The

following performance characteristics must be tested:

(i) Mechanical integrity testing.

(ii) Testing to determine temperature change rate(s).

(iii) Testing to demonstrate compatibility with the indicated external controller.

(iv) Shelf life testing.

(3) Animal testing must demonstrate that the device does not cause esophageal injury and that body temperature remains within appropriate boundaries under anticipated conditions of use.

(4) Labeling must include the following:

(i) Detailed insertion instructions.

(ii) Warning against attaching the device to unintended connections, such as external controllers for which the device is not indicated, or pressurized air outlets instead of vacuum outlets for those devices, including gastric suction.

(iii) The operating parameters, name, and model number of the indicated external controller.

(iv) The intended duration of use.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20317 Filed 8–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1902, 1903, 1904, 1952, 1953, 1954, 1955, and 1956

[Docket No. OSHA–2014–0009]

RIN 1218–AC76

Streamlining of Provisions on State Plans for Occupational Safety and Health

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Direct final rule.

SUMMARY: This document primarily amends OSHA regulations to remove the detailed descriptions of State plan coverage, purely historical data, and other unnecessarily codified information. In addition, this document moves most of the general provisions of subpart A of part 1952 into part 1902, where the general regulations on State plan criteria are found. It also amends several other OSHA regulations to delete references to part 1952, which will no longer apply. The purpose of these revisions is to eliminate the unnecessary codification of material in the Code of Federal Regulations and thus save the time and funds currently expended in publicizing State plan revisions. The streamlining of OSHA State plan regulations does not change the areas of coverage or any other substantive components of any State plan. It also does not affect the rights and responsibilities of the State plans, or any employers or employees, except to eliminate the burden on State plan designees to keep paper copies of approved State plans and plan supplements in an office, and to submit multiple copies of proposed State plan documents to OSHA. This document also contains a request for comments for an Information Collection Request (ICR) under the Paperwork Reduction Act of 1995 (PRA), which covers all collection of information requirements in OSHA State plan regulations.

DATES: This direct final rule is effective October 19, 2015. Comments and additional materials (including comments on the information-collection (paperwork) determination described under the section titled **SUPPLEMENTARY INFORMATION** of this document) must be submitted (post-marked, sent or received) by September 17, 2015.

ADDRESSES: You may submit comments, identified by docket number OSHA–2014–0009, or regulatory information number (RIN) 1218–AC76 by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal. Follow the instructions on-line for making electronic submissions; or

Fax: If your submission, including attachments, does not exceed 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648; or

U.S. mail, hand delivery, express mail, messenger or courier service: You must submit your comments and attachments to the OSHA Docket Office, Docket No OSHA–2014–0009, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., EST.

Instructions for submitting comments: All submissions must include the Docket Number (Docket No. OSHA–2014–0009) or the RIN number (RIN 1218–AC76) for this rulemaking. Because of security-related procedures, submission by regular mail may result in significant delay. Please contact the OSHA Docket Office for information about security procedures for making submissions by hand delivery, express delivery and messenger or courier service.

All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, caution should be taken in submitting personal information, such as Social Security numbers and birth dates.

Docket: To read or download submissions in response to this **Federal Register** document, go to docket number OSHA–2014–0009, at *http://www.regulations.gov.* All submissions are listed in the *http://www.regulations.gov* index: However, some information (*e.g.*, copyrighted material) is not publicly available to read or download through that Web page. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://www.regulations.gov.* This document, as well as news releases and other relevant information, is available at OSHA's Web page at *http://www.osha.gov.* A copy of the documents referenced in this document may be obtained from: Office of State Programs, Directorate of Cooperative and State Programs, Occupational Safety and Health Administration, Room N3700, 200 Constitution Avenue NW., Washington, DC 20210, (202) 693–2244, fax (202) 693–1671.

FOR FURTHER INFORMATION CONTACT: *For press inquiries:* Francis Meilinger, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general and technical information: Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N–3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone: (202) 693–2200; email: *kalinowski.doug@dol.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 18 of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 667, provides that States that desire to assume responsibility for the development and enforcement of