



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2017-N-1914]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Closed Loop
Hysteroscopic Insufflator with Cutter-Coagulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the closed loop hysteroscopic insufflator with cutter-coagulator 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 closed loop hysteroscopic insufflator with cutter-coagulator 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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on March 28, 2014.

FOR FURTHER INFORMATION CONTACT: Veronica Price, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G116, Silver Spring, MD 20993-0002, 301-796-6538.

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, also known as De Novo classification, 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) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of

substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

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

On September 5, 2013, IOGYN, Inc., submitted a request for classification of the IOGYN System, Models FG-0200, FG-0201, and FG-0202 under section 513(f)(2) of the FD&C Act.

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 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 March 28, 2014, 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 884.1710.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a closed loop hysteroscopic insufflator with cutter-coagulator will need to comply with the special controls named in the final order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or premarket approval application in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome pathway of 510(k), when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name closed loop hysteroscopic insufflator with cutter-coagulator, and it is identified as a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (i.e., resection and coagulation). This device type contains a closed loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.

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

Table 1.--Closed Loop Hysteroscopic Insufflator with Cutter-Coagulator Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Adverse tissue reaction	Biocompatibility Labeling
Equipment malfunction leading to injury	Non-clinical Performance Testing Software Verification, Validation, and Hazards Analysis Labeling Training

Recirculated fluid causes adverse tissue reaction	Biocompatibility Non-clinical Performance Testing
Fluid overload, embolism, perforation or other adverse events	Non-clinical Performance Testing Software Verification, Validation, and Hazards Analysis Labeling Training
Infection	Sterility Shelf Life Testing Non-clinical Performance Testing
Electromagnetic interference/electrical safety issues	Electromagnetic Compatibility Testing Electrical Safety Testing Labeling
Operator error leading to patient injury	Labeling Training

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

Closed loop hysteroscopic insufflators with cutter-coagulator are not safe for use except under the supervision of a practitioner licensed by law to direct use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (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 (510(k)), prior to marketing the device, which contains information on the closed loop hysteroscopic insufflator with cutter-coagulator they intend to market.

II. Analysis of Environmental Impact

We have 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 part 801 regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 884

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 884 is amended as follows:

PART 884--OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for part 884 is revised to read as follows:

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

2. Add § 884.1710 to subpart B to read as follows:

§ 884.1710 Closed loop hysteroscopic insufflator with cutter-coagulator.

(a) Identification. A closed loop hysteroscopic insufflator with cutter-coagulator is a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (i.e., resection and coagulation). This device type contains a closed-loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

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

(3) Electrical equipment safety, including appropriate thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed.

(4) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6} .

(5) Shelf-life testing that demonstrates the device packaging maintains sterility and the functionality of the device is maintained following simulated shipping and handling must be provided to support the proposed shelf life.

(6) Non-clinical testing data must demonstrate the performance characteristics of the device. Detailed protocols and the test reports must be provided for each test.

(i) The following tests must be performed for the resection portion of the device:

(A) Mechanical testing to assess critical joint strength.

(B) Device electrode temperature testing.

(C) Coagulation depth testing.

(D) Simulated use testing.

(E) Device durability testing.

(ii) The following tests must be performed for the fluid management portion of the device:

(A) Mechanical testing to assess tensile strength of connections.

(B) Pressure testing that demonstrates the following parameters, including accuracy of the pressure displayed; appropriate detection and response to overpressure conditions; activation of a secondary overpressure relief valve at the maximum safe level; and all accessories within the fluid path meet the pressure requirements.

(C) Fluid delivery volume testing that demonstrates that the maximum fluid volume delivered is below a predefined level.

(D) Flow rate testing.

(E) Simulated use testing.

(F) Filtration testing.

(G) Blood filtration capacity testing.

(H) Tissue collection capacity testing.

(I) Filtrate characterization and testing that demonstrates that the continuous reintroduction of filtrate into the uterus does not pose a safety risk.

(7) Clinician labeling must include:

(i) Specific instructions and the clinical training needed for the safe use of the device.

(ii) Appropriate warnings, precautions, and information related to overpressurization.

(iii) Appropriate EMC information.

(iv) An expiration date/shelf life.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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