DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 28, 2014

IOGYN, Inc.
% Mary J. Edwards
Regulatory Consultant
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Re: K132695
IOGYN System, Models FG-0200, FG-0201, FG-0202
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 884.1710
Regulation Name: Closed Loop Hysteroscopic Insufflator with Cutter-coagulator
Regulatory Classification: Class II
Product Code: PGT
Dated: September 5, 2013
Received: September 6, 2013

Dear Mary J. Edwards:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the IOGYN System, a prescription device under 21 CFR Part 801.109 that is indicated for distension of the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for cutting and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device. FDA concludes that this device should be classified into class II. This order, therefore, classifies the IOGYN System, and substantially equivalent devices of this generic type, into class II under the generic name, Closed Loop Hysteroscopic Insufflator with Cutter-coagulator.

FDA identifies this generic type of device as:

> **Closed Loop Hysteroscopic Insufflator with Cutter-coagulator:** 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.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On September 6, 2013, FDA received your *de novo* requesting classification of the IOGYN System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the IOGYN System into class I or II, it is necessary that the proposed class have sufficient regulatory 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 *de novo* request, FDA has determined that the IOGYN System indicated for distension of the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for cutting and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Adverse tissue reaction	Biocompatibility Labeling
Equipment malfunction leading to injury	Non-clinical Performance Testing Software Verification, Validation & 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 & 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

In combination with the general controls of the FD&C Act, the Closed Loop Hysteroscopic Insufflator with Cutter-coagulator is subject to the following special controls:

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.
    a. The following tests must be performed for the resection portion of the device:
        - Mechanical testing to assess critical joint strength
        - Device electrode temperature testing
        - Coagulation depth testing
        - Simulated use testing
        - Device durability testing
    b. The following tests must be performed for the fluid management portion of the device:
        - Mechanical testing to assess tensile strength of connections
        - 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.

- Fluid delivery volume testing that demonstrates that the maximum fluid volume delivered is below a predefined level.
- Flow rate testing
- Simulated use testing
- Filtration testing
- Blood filtration capacity testing
- Tissue collection capacity testing
- 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:
   - Specific instructions and the clinical training needed for the safe use of the device.
   - Appropriate warnings, precautions and information related to over pressurization.
   - Appropriate EMC information
   - An expiration date/shelf life

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Closed Loop Hysteroscopic Insufflator with Cutter-coagulator they intend to market prior to marketing the device and receive clearance to market from FDA

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Veronica Price at 301-796-6538.

Sincerely yours,

Jonette R. Foy -S

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