K123330
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MAR 19 2013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: March 14, 2013

Submitter:

Name:	IOGYN, Inc.
Address:	20195 Stevens Creek Blvd., Ste. 120 Cupertino, CA 95014
Contact Person:	Mary Edwards
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Product:

Trade Name:	IOGYN Endoscope
Common Name:	Endoscope
Classification Name:	Hysteroscope

Predicate Device:

- K991563 – Hysteroscopic Resectoscope

Device Description: The IOGYN Endoscope is a rigid multi-channel endoscope provided with a rod lens system to transmit light and images, a working channel, and two fluid channels. The body consists of an outer and an inner tube of surgical steel. The light fibers, rod-lens optical system, and two fluid channels are sandwiched between these tubes. The inner tube serves as a working channel to provide access for resection/coagulation instruments. The fluid channels are intended to move fluid. At the proximal end, the endoscope is provided with a light post that is compatible with standard endoscopic light sources, and with an eyepiece intended for visualization.

The IOGYN Endoscope is dimensionally compatible with the IOGYN System.

Indications for Use: The IOGYN Endoscope is intended to provide the physician with a means for endoscopic diagnostic and therapeutic surgical procedures. It is indicated for use in diagnostic examination and therapeutic surgical procedures of, but not limited to, urology and gynecology.

Performance Data: Testing was performed according to IEC 60601-2-18. Thermal testing and simulated use testing were performed to support safety and effectiveness and substantial equivalence to the predicate device. The

IOGYN Endoscope met all specified design and performance requirements.

Technological Characteristics The technological and performance characteristics of the device are similar to those of the predicate devices, as shown by the following summary table:

	Subject Device	**Predicate Device**	**Reference Device**
510(k) No.	**Pending**	**K991563**	**K082841**
Device	Endoscope	Hysteroscopic Resectoscope [and Accessories]	Foraminoscope
510(k) Sponsor	IOGYN, Inc. (Specification Developer)	Henke-Sass Wolf of America, Inc.	Blazejewski Medi-Tech GmbH
Intended Use	To enable the viewing and to provide access for resection/coagulation of soft tissue encountered in, but not limited to, diagnostic and surgical procedures in gynecology and urology.	To enable the viewing and to provide access for resection/coagulation of soft tissue encountered in, but not limited to, diagnostic and surgical procedures in gynecology and urology.	For endoscopic visualization and to provide access for surgical procedures of the lumbar and cervical spine.
Materials	Stainless Steel, Sapphire Glass, Fiberglass	Stainless Steel, Titanium, Sapphire Glass, Fiberglass	Stainless Steel, Sapphire Glass, Fiberglass
Sterility	Non-sterile	Non-sterile	Non-sterile
Reusable	Yes	Yes	Yes

Conclusion: The information provided in this 510(k) submission provides reasonable assurance that the subject device IOGYN Endoscope is safe and effective and that it is substantially equivalent to the predicate and reference devices with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

IOGYN, Inc.
% Ms. Mary J. Edwards
Regulatory Consultant
Regulatory & Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
MINNEAPOLIS MN 55416

Re: K123330
Trade/Device Name: IOGYN ENDOSCOPE
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: March 7, 2013
Received: March 11, 2013

Dear Ms. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123330

Device Name: IOGYN ENDOSCOPE

Indications for Use: The IOGYN Endoscope is intended to provide the physician with a means for endoscopic diagnostic and therapeutic surgical procedures. It is indicated for use in diagnostic examination and therapeutic surgical procedures of, but not limited to, urology and gynecology.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123330