Optim LLC
A Juno Company

APR 19 2013

7.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92.

Jeff Barrett, CEO
Optim LLC
64 Technology Park Rd.
Sturbridge, MA 01566

Date Prepared: 17 April 2013

Device Trade Name: Precision Endoscopic Infrared Coagulator; Model 5100 Single-Use disposable Maxi-guide Flexible Lightguide; Model 5100-2

Device Classification Name: Electrode, Flexible Suction Coagulator
Registration Number: 1218141
Regulation Number: 876.4300
Product Code: FEH
Classification: Class II
Review Panel: Gastroenterology / Urology
Predicate Device Information

- Precision Endoscopic Infrared Coagulator; Model 5100 Single-Use disposable Maxi-guide Flexible Lightguide; Model 5100-2 (K122593); Precision Endoscopic Technologies, Inc.
- Precision Endoscopic Infrared Coagulator; Model 5100 Single-Use disposable Maxi-guide Flexible Lightguide; Model 5100-2 (K083275); MAX Endoscopy, Inc.

Submission Device Description:
This device is designed to coagulate blood and tissue, specifically for treatment of hemorrhoids and small lesions in the colon and rectum, when used as an accessory to a flexible endoscope.

Statement of Intended Use

The PRECISION Endoscopic Infrared Coagulator with single-use disposable MAXiguide flexible light guide is intended for treatment of hemorrhoids and other lesions in the colon and rectum by the transmission of infrared energy when used as an accessory to a colonoscope, flexible sigmoidoscope, or other flexible gastrointestinal endoscope.

Substantial Equivalence Summary
There are no technology differences between the predicate devices and the submission device. This change is a design and labeling change to address customer needs. There are no changes to the intended use or indications for use. The purpose of the devices is to provide infrared energy to coagulate blood and tissue. The predicate devices and the submission device deliver infrared energy from a lamp using a light guide for treatment of hemorrhoids and small lesions in the colon and rectum.

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Non Clinical Verification Testing
Verification testing results for the design changes were completed and all tests passed. Bench testing was performed to verify that the submission device is substantially equivalent to the predicate devices and does not affect the safety and effectiveness of the device.

Conclusion: The submission device is substantially equivalent and as safe and effective as the predicate devices.

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

April 19, 2013

Optim, LLC
% Mr. Jeff Barrett
CEO
64 Technology Park Road
STURBRIDGE MA 01566

Re: K130489
Trade/Device Name: PRECISION Endoscopic Infrared Coagulator™ with SINGLE-USE DISPOSABLE MAXI-GUIDE FLEXIBLE LIGHTGUIDE
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FEH
Dated: April 10, 2013
Received: April 16, 2013

Dear Mr. Barrett:

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,

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

Optim LLC
A Hologic Company

Indications for Use

510(k) number (if known): **K130489**

Device name: PRECISION Endoscopic Infrared Coagulator™ with SINGLE- USE DISPOSABLE MAXI-GUIDE FLEXIBLE LIGHTGUIDE

Statement of Indication of Use

The PRECISION Endoscopic Infrared Coagulator with single-use disposable MAXiguide flexible light guide is intended for treatment of hemorrhoids and other lesions in the colon and rectum by the transmission of infrared energy when used as an accessory to a colonoscope, flexible sigmoidoscope, or other flexible gastrointestinal endoscope.

Prescription Use_____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R Fisher -S
2013.04.19 14:34:50 -04'00'

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