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

July 26, 2016

MedKey, LLC
Babacar Diouf
Catheter Research, Inc.
5610 W. 82nd Street
Indianapolis, IN 46278

Re: K153124
Trade/Device Name: DuraLaze HoLEP Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 22, 2016
Received: June 23, 2016

Dear Babacar Diouf:

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 Parts 801 and 809); 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153124

Device Name
DuraLaze™ HoLEP Laser Fiber

Indications for Use *(Describe)*
The DuraLaze™ HoLEP Laser Fiber is intended for use in laser enabled endoscopic surgery to enucleate, vaporize, maintain hemostasis, and excise prostate tissue associated with benign prostatic hyperplasia (BPH). The DuraLaze™ HoLEP Laser Fiber is supplied ETO sterilized and is intended for single use only. It is specifically designed for use with Ho:YAG laser systems, with regulatory clearance for surgical use and compatible with a standard SMA-905 connector.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

Applicant/Sponsor: MedKey, LLC.
2620 N. Walnut Street, Suite 1205
Bloomington, Indiana 47404

Contact Person: Babacar Diouf
VP of RA and QS
CRI
317-872-0074 x3512
bdiouf@cri-devices.com

Date Prepared: April 4th, 2016

Device Name:

Proprietary Name:	DuraLaze™ HoLEP Laser Fiber
Classification Name:	Powered Laser Surgical Instrument
Review Panel:	General and Plastic Surgery
Product Code:	GEX
Classification Regulation:	21 CFR 878.4810. Class II

Predicate Device (Legally Marketed Devices to Which Substantial Equivalence Is Claimed):

Proprietary Name:	Lumenis VersaPulse PowerSuite
Classification Name:	Powered Laser Surgical Instrument (and Accessories)
Review Panel:	General and Plastic Surgery and Dermatology
Product Code:	GEX
Classification Regulation:	21 CFR 878.4810. Class II
Premarket Notification:	**K011703**

Secondary Predicate (Used to Substantiate Technological Characteristics' Equivalency):

Proprietary Name:	AccuMax™
Classification Name:	Powered Laser Surgical Instrument
Review Panel:	General and Plastic Surgery and Dermatology
Product Code:	GEX
Classification Regulation:	21 CFR 878.4810. Class II
Premarket Notification:	**K093691**

Device Description:

The DuraLaze™ HoLEP Laser Fiber is a straight fire fiber optic laser energy delivery device. The laser fiber contains a 550µm silica core jacketed with ethylene tetrafluoroethylene (ETFE) and a standard SMA-905 laser connector with a strain relief. The distal 10 cm of the ETFE jacket is pre-stripped and coated during the manufacture of the laser fiber to minimize the potential of laser fiber damage caused by jacket stripping during surgical use and for the convenience of the operating room staff. The pre-stripped distal

tip comes with a printed axial line that improves the surgeon's visibility by increasing the contrast between the fiber tip and the surrounding tissue. The DuraLaze™ HoLEP Laser Fiber is contained within a 9 French, polyurethane stability sheath that holds and secures the laser fiber during surgical use. The DuraLaze™ HoLEP Laser Fiber is supplied ETO sterilized and is intended for single use. It is specifically designed for use with Ho:YAG laser systems, with regulatory clearance for surgical use and compatible with a standard SMA-905 connector.

Indications for use:

The DuraLaze™ HoLEP Laser Fiber is intended for use in laser enabled endoscopic surgery to enucleate, vaporize, maintain hemostasis, and excise prostate tissue associated with benign prostatic hyperplasia (BPH). The DuraLaze™ HoLEP Laser Fiber is supplied ETO sterilized and is intended for single use only. It is specifically designed for use with Ho:YAG laser systems, with regulatory clearance for surgical use and compatible with a standard SMA-905 connector.

Technological Characteristics:

The DuraLaze™ HoLEP Laser Fiber is substantially equivalent in technological characteristics and fundamental design to its predicates. The materials and dimensions of the subject device and its predicates are comparable with the exception of the fiber's stripped distal tip. The DuraLaze™ HoLEP Fiber distal tip is pre-stripped 10.0 cm to minimize potential of laser fiber damage caused by stripping the jacket during surgery, whereas the predicate device(s) fiber distal tip is pre-stripped 0.4 cm, which requires additional stripping during use. The subject device distal tip is also printed with an axial line that improves the surgeon's visibility.

Reference the table below for details.

Technological Characteristics	Primary Predicate Device Name: Lumenis VersaPulse PowerSuite	Secondary Predicate Device Name: AccuMax™	Proposed Device Name: DuraLaze™ HoLEP Laser Fiber
Energy Specifications			
Energy type	Ho:YAG / ND:YAG laser energy	Ho:YAG laser energy	Ho:YAG laser energy
Max. Input Wattage	100 Watts - 550µm core fiber	100 Watts - 550µm core fiber	100 Watts - 550µm core fiber
Dimensional Specifications			
Laser Fiber:			
Core Size	550µm	550µm	550µm
Outside Diameter	780 µm	750 µm	750 µm
Working Length	2.5 m	2.6 m	2.6 m
Distal tip:ETFE jacket stripped length	0.4 cm	0.4 cm	10.0 cm
Sheath:			
Sheath	Provided Separately	Provided Separately	Fiber is placed in sheath
Sheath OD	7 French	7 French	9 French
Sheath length	N/A	N/A	36 cm
Sheath Tip ID	N/A	N/A	0.030 in
Materials (Individual components)			
Fiber Core	Silica	Silica	Silica
Fiber Jacket	Tetrafluoroethylene (ETFE)	Tetrafluoroethylene (ETFE)	Tetrafluoroethylene (ETFE)
Coating - Distal Fiber Tip	N/A	N/A	Acrylate coating: 10cm
Strain Relief - Laser Fiber to SMA-905 Connector	Unknown Polymer	Sanoprene	Sanoprene
Sheath	Provided Separately	Provided Separately	Polyurethane tubing
Tuohy Borst Adapter for sheath	N/A	N/A	Fluoropolymer seal & Polycarbonate housing
Laser Fiber Connector	SMA-905 Connector	SMA-905 Connector	SMA-905 Connector
Tip Marking	Not included	Not included	Marabou Ink, Axial 10cm distal line
Packaging Pouch	Tyvek Pouch	Tyvek Pouch	Tyvek Pouch

Substantial Equivalence:
A direct comparison of key characteristics demonstrates that the DuraLaze™ HoLEP Laser Fiber is substantially equivalent to its predicates in terms of intended use, technological characteristics, and performance characteristics.

Non-Clinical Testing / Performance Testing (Bench Evaluation):
MedKey has conducted performance testing with samples aged at T=0 and T=1 year accelerated aging in support of the proposed laser device. The following testing was completed to evaluate the safety and effectiveness of the proposed device:

- Fiber Energy Transmission
- Fiber & Stability Sheath Interactions
- Fiber Dimensions
- Fiber Bend Radius
- Distal Fiber Coated OD
- Fiber Stability Sheath Dimensions and Functionality
- Fiber Connector Strength
- Connector Tensile
- Aiming Beam
- Packaging integrity Testing per ISO 11607-1:2006
- Biological evaluation of medical devices per ISO10993-1:2009
- ETO Sterilization validation per ISO 11135-1:2007

Conclusion:
The testing and assessments performed on the subject device meet all specified criteria. The results of the performance testing demonstrate that the DuraLaze™ HoLEP Laser Fiber is substantially equivalent to the predicate device.