JAN - 8 2014

K130681 - 510(k) Summary
Endovascular Laser Venous System Kit with 2 Ring Radial Emitting Fiber

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Biolitec SIA
Kaniera iela 10a, Riga, LV-1063
Latvia
Phone: * (413) 525-0600 or 413-250-0779
Facsimile: * (413) 525-0611

Contact Person: *Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: March 4, 2013

Name of Device and Name/Address of Sponsor

Endovascular Laser Venous System Kit (ELVeS®) with 2 Ring Radial Fiber
Biolitec SIA
Kaniera iela 10a, Riga, LV-1063
Latvia

Classification Name

Surgical laser accessories

Predicate Devices

ELVeS Kit with Radial Fiber

Intended Use/Indication for Use

The device is intended for endovascular coagulation of blood vessels. The device is indicated for the endovascular coagulation of the Greater Saphenous Vein of the thigh in patients with superficial vein reflux.

Technological Characteristics

The ELVeS kit with 2 Ring Radial Fibers contain the following components: (1) 2 ring radial fiber; (2) access needle; (3) introducer sheath/ dilator; and (4) a guidewire and is identical to that cleared under K101712 and K112299 except for the 2 ring radial tip design. The design provides 2 adjacent points of radial emission.

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 601-1; IEC 601-2-22; EN 60825-1, and ANSI/AAMI/ISO 10993-7.

The clinical effectiveness is equivalent to its predicate devices, as evidence by several clinical evaluations.

In one study, the circumferential ablation of the vein with introduction of the 2 ring radial fiber provided a better outcome following EVLA: 1) reduction in recanalization rates 2) reduction in applied Watt/LEED, & 3) reduction in adverse events; including bruising, pain, induration & numbness. The study supported the conclusion concluded that EVLA with 2-ring radial fiber for GSV and SSV is an effective and safe procedure, giving the advantage of decreasing delivered energy during the procedure and also providing very good occlusion rates with lowered rates of side/adverse effects.

Another study demonstrated an effective method to treat large insufficient GSV (diameter above 8 mm) by using the 2 ring radial-fiber. The procedure needed less energy and resulted in an optimal homogenous radiation. The patient satisfaction rate was high and the clinical evaluators could demonstrate that modified CEAP severity was much better after 1&2 days. No significant difference was observed in the occlusion-rate between subgroups of >8mm dia. and <8mm dia.

A further study compared the efficacy, adverse events, occlusion rates, patient satisfaction and changes in venous clinical severity scores in the treatment of very large diameter (>12 mm) greater saphenous veins (GSV) with the 2 ring radial fiber compared to radio frequency (RF) energy. VCSS scores were improved after the procedures and there was no statistically significant difference between groups. There was also no statistically significant difference in patient satisfaction between groups. Both treatment modalities were safe and effective in the treatment of very large diameter GSVs. The 2-ring radial fiber also resulted in almost no pain.

Sterilization cycle parameters and the validation reports showed an acceptable sterility was achieved with the device.

Substantial Equivalence

The ELVeS with 2 Ring Radial Fiber is substantially identical to that cleared under K101712 and K112299 and has the same intended use and indications for use as the cleared Evolve HPD 980-1470nm Multiwavelength and Ceralas 1470, 980 and 810nm ELVeS kits. Thus, the ELVeS with 2 Ring Radial Fiber is substantially equivalent to its 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

Biolitec SIA
Dr. Harry Hayes
Regulatory Consultant
Kaniera iela 10a
Riga, LV-1063
Latvia

January 8, 2014

Re: K130681
Trade/Device Name: Endo Laser Vein System Kit with 2 Ring Radial 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: November 22, 2013
Received: December 11, 2013

Dear Dr. Hayes:

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 contact 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. 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,

Joshua C. Nipper -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_____K130681_____

Device Name: **Endo Laser Vein System Kit with 2 Ring Radial Fiber**

Endovascular Coagulation of the Greater Saphenous Vein of the thigh in patients with superficial vein reflux.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√__ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Neil R Ogden -S
2014.01.06 13:16:40 -05'00'

(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K130681