DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 9, 2016

Diotech Co.
% Mr. Peter Chung
Official Correspondent
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152667
Trade/Device Name: ATOVEN-Reusable 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: March 4, 2016
Received: March 11, 2016

Dear Mr. Chung:

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 ; 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, 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" (21 CFR 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 Post-market 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,

Jennifer R. Stevenson -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)*
K152667

Device Name
ATOVEN Reusable Laser Fiber

Indications for Use *(Describe)*

ATOVEN-Reusable Laser Fiber is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux. for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.
The ATOVEN-Reusable Laser Fiber may be used with CW laser with wavelength range 810-1470 nm, a power range 5-15W, using an SMA905 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (K152667)

[as required by 807.92(c)]

1. Applicant Information

1) Company : Diotech Co.
2) Address : 301, Nakdong-daero, Saha-gu, Busan, Korea
3) Device : ATOVEN-Reusable Laser Fiber
4) Phone Number : +82-51-292-6237
5) Fax Number : +82-51-292-6258
6) Homepage: http://www.diotech21.com

2. Device Information

1) Trade Name : ATOVEN-Reusable Laser Fiber (Model name : DLF147-7)
2) Common Name : Diode Laser
3) Regulation Name : Laser surgical instrument for use in general and plastic surgery and in dermatology
4) Product code : GEX
5) Regulation number : 878.4810
6) Class of device : Class II

3. The legally marketed device to which we are claiming equivalence

K140458, K140366

4. Description of device

ATOVEN-Reusable Laser Fiber is free-beam delivery device that transits laser energy into intended direction. Fiber length is 2.9mters. This device can be connected with SMA905 connector and deliver to 810~1470㎛. This device can be connected with cleared surgical use laser diode.

5. Intended Use

ATOVEN-Reusable Laser Fiber is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.
The ATOVEN-Reusable Laser Fiber may be used with CW laser with wavelength range 810~1470nm, a power range 5~15W, using an SMA905 connector.

6. Technological Characteristics

ATOVEN-Reusable Laser Fiber consists of optic fiber. The optic fiber also consists of connector, optical fiber. Fiber cable is made of the optical fiber that delivers the laser beam. And the fiber may be used any laser wavelength between 810~1470 ㎛ that have been cleared for surgical use diode laser. Outer diameter of fiber cable is 0.6mm and length is 2900 ㎜.
The fiber core and cladding for the subject device are made from silica which is the same material used in the predicate device. This device can be connected with SMA905 connector.

7. Performance

Bench tests were performed. Bench testing included biocompatibility. The tests demonstrated that the device is as safe, as effective and performs in a substantially equivalent manner to the predicate device.

Bench test

Radiopacity, flexural strength, tensile strength, drop out, breakdown, appearance, dimension, laser transfer efficiency test, integrity test, fiber transmission angle tip test, simulated clinical evironment test, fiber transmission angle test (with glass and without glass) and Dimension comparison test

Biocompatibility test

Hemolysis, cytotoxicity, intracutaneous reactivity, maximization sensitization, pyrogen and acute systemic toxicity

8. Predicate device comparison table

Predicate device – Diotech Laser Fibers (K140458)

The ATOVEN-Reusable Laser Fiber have a identical intended use to the Diotech Laser Fibers in that they are indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.
And raw material, dimension, structure and components are identical. The different is ATOVEN-Reusable Laser Fiber is not single use and this device is reusable.

Predicate device – Hogue Surgical EndlessFiber Reusable Surgical Laser Fiber (K140366)

The ATOVEN-Reusable Laser Fiber is similar intended use to the Reusable Surgical Laser Fiber for patient vein. These devices are using identical connector SMA905 and have similar raw material, dimension, structure and components. The wavelength range is similar that proposed device's wavelength range is 810~1470nm and K140366's wavelength range is 532~2200nm. These devices are reusable.

9. Conclusion

The Device is investigated for function and effectiveness to compare the operation of function between ATOVEN-Reusable Laser Fiber and predicate devices.
Comparison results demonstrate that the specifications and performance of the device are similar as functional and effective as the legally marketed predicate device.
Therefore, it is concluded that ATOVEN-Reusable Laser Fiber is substantially equivalent to the legally marketed predicate device.