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

Adler MicroMed Incorporated
Mr. Brian Chandler
Chief Executive Officer
6842 Elaine Way
San Diego, California 92120

December 1, 2015

Re: K152417
Trade/Device Name: Adler MicroMed Laser Surgery Fibers
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: September 10, 2015
Received: September 10, 2015

Dear Mr. Chandler:

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 [SELECT ONE: Part 801 [or, for IVDs only] 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,

Joshua C. Nipper -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)*
K152417

Device Name
Adler MicroMed Laser Surgery Fibers

Indications for Use *(Describe)*
The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision,tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

The Adler MicroMed Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an 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.

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

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510(k) SUMMARY

Title: Adler MicroMed Surgical Laser Fibers

Submitter: Adler MicroMed, Inc.,
6842 Elaine Way San Diego
California 92120
USA

Contact: Brian Chandler
Tittle : CEO
Phone : 484-995-7919
E-Mail: bchandler@adlermicromed.com
Address: 6842 Elaine Way San Diego
California 92120
USA

Date Prepared: July 12, 2015

Device Trade Name: Adler MicroMed Surgical Laser Fibers

Common Name: Fiber Optic laser delivery system

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Device product code:
GEX

Device Classification 21 CFR 878.4810

Predicate Device: Oberon Laser Surgery Fiber, K140470

Device Description:
The Adler MicroMed Laser Surgery Fibers are single use laser delivery devices provided sterile and intended for medical applications in various fields of laser surgery.

The devices are based on a silica quartz glass core, have a length range of 6.5 feet (2 meters) to 9.8 feet (3 meters) and a wavelength range between 450 and 2100nm.
The proximal end of the fibers is connected to a cleared laser system via an SMA 905 connector, while the distal end delivers the laser energy to the target tissue inn pulsed and continuous wave mode.

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The distal end may have a rounded or conical silica cap, or non-capped tips, which may be flat, spherical, ball, conical or bended for the various intended uses and effects.

Intended Use:
The Fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. It is also indicated for use in open or closed endoscopic applications where incision, excision,tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

The Adler MicroMed Laser Surgery Fibers have a wavelength range of 450 nm to 2100 nm, can be used in contact and non-contact mode and are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT and endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.

Substantial Equivalence:
The Adler MicroMed Laser Surgery Fibers have the same mechanism of action, same intended use and the same technological characteristics as the predicate devices, the Oberon Laser Surgery Fibers, (K140470).

Non clinical Performance Data :
The following performance tests has been conducted in order to demonstrate that the Adler Laser Surgery Fibers are as safe and as effective as the cleared predicate devices:

Sterilization	Sterilization Validation SAL Evaluation EO Validation
Packaging	Packaging Validation Package Integrity Package Sealing Validation
Shelf Life	Shelf Life Validation
Biocompatibility	Biocompatibility testing relevant to products
Functional	Aging test, Energy transmission validation

Clinical Performance data: None

Conclusion:
Based on above, we conclude that equivalence has been demostrated and that Adler MicroMed Laser Surgery Fibers are as safe and effective as the predicate device.