



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 16, 2016

A.R.C. Laser GmbH
Ms. Angela Thyzel
CEO
Bessemer St. 14
Nurnberg, 90411
Germany

Re: K161403

Trade/Device Name: A.R.C. Laser Surgical Fibers And Probes

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: May 20, 2016

Received: May 20, 2016

Dear Ms. Thyzel:

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 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,


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

Indications for Use

510(k) Number (if known)
K161403

Device Name
A.R.C Laser Surgery Fibers and Probes

Indications for Use (Describe)

The A.R.C laser surgery fibers and probes are intended for delivery of laser energy to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue.

The A.R.C laser surgery fibers and probes are indicated for use in General Surgery, Urology, Gynecology and ENT 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



Section 5 - 510(k) SUMMARY

Title: A.R.C. Laser Surgical Laser Fibers & Probes

Submitter: A.R.C. Laser GmbH
Bessemer St. 14
90411, Nurnberg
Germany

Contact : Angela Thyzel
Tittle : General Manager
Phone : 0911-21779-0
Fax : 0911-21779-99
E-Mail: a.thyzel@arclaser.de
Address: Bessemer St. 14
90411, Nurnberg
Germany

Date
Prepared: May 15, 2016

Device Trade
Name: A.R.C. Laser Surgical Laser Fibers & Probes

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
Devices: Adler MicroMed Surgical Laser Fibers (K152417)

Device
Description: The A.R.C. surgical laser fibers & probes are single use laser delivery devices provided EO sterile and intended for medical applications in various fields of laser surgery.
The devices are based on a quartz core, have a length of 6.5 feet (2 meters) to 9.9 feet (3 meters) and a wavelength range between 450nm to 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 in pulsed and continuous wave mode.

The distal end have a bare tip which may be flat or spherical, and may be used with a variety of sterile hand pieces for the various intended uses and effects.

Intended

Use: The A.R.C. laser surgery fibers & probes are intended for delivery of laser energy to soft tissue in the contact and non-contact mode during surgical procedures, including via endoscopes. The fibers are indicated for use in general surgical applications for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue.

The A.R.C. Laser Surgery Fibers & Probes are indicated for use in General Surgery, Urology, Gynecology and ENT with a cleared compatible laser marketed for the mentioned intended uses and using an SMA 905 connector.

**Substantial
Equivalence:**

The A.R.C. laser surgery fibers & probes have the same mechanism of action, same intended use and the same technological characteristics as the predicate devices, the Adler MicroMed Laser Surgery Fibers, K152417.

Thus, we conclude that the A.R.C. Laser Surgery Fibers & Probes are as safe and effective as the predicate devices.

Performance

Bench Testing : The A.R.C. laser surgery fibers & probes are single use and sterile medical devices, thus the following tests have been performed

| Test | Standard/ Guidelines | Section in submission |
|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Bench, functional tests | Internal methods | Section 11 <i>Fibers functional aging test</i> <i>Fibers Energy transmission validation</i> |
| Sterile packaging test: Visual packaging integrity test Sealing strength validation Microbial barrier Peel test | ASTM F1886/F1886M-09: 2013 ASTM F1980-07:2001 ASTM F1608-00:2009 DIN EN ISO 11737-2:2014 DIN EN 868:2009 ISO 10993-1:2009(R) 2013 EN ISO 11607-1 | Section 13 <i>Packaging</i> <i>Shelf Life</i> |
| Sterilization validation | DIN EN ISO 11135-1:2014 ISO 10993-7: 2009 | Section 14 <i>Appendix 8-Sterilization Validation -EO Residuals</i> |



The performance testing demonstrated that the A.R.C. laser surgery fibers & probes are as safe and as effective as the cleared predicate devices.

Clinical
Performance
data: None