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

September 27, 2017

A.R.C. Laser GmbH
% Angela Thyzel
General Manager
Bessemer St. 14
Nurnberg, 90411 DE

Re: K170183
Trade/Device Name: Cetus System, Cetus Probe
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting Instrument
Regulatory Class: Class II
Product Code: HQE
Dated: August 24, 2017
Received: August 24, 2017

Dear Angela 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 (DICE) 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 Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

Bradley S. Cunningham -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170183

Device Name
Cetus System

Indications for Use *(Describe)*
The Cetus Laser System is indicated for use in phacofragmentation of the cataractous crystalline lens.

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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K170183

510(k) SUMMARY

Title:	A.R.C. Cetus System
Submitter:	A.R.C. Laser GmbH Bessemer St. 14 90411, Nurnberg Germany
Contact :	Angela Thyzel
Tittle :	General Manager
Phone :	0911-21779-0
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E-Mail:	a.thyzel@arclaser.de
Address:	Bessemer St. 14 90411, Nurnberg Germany
Date Prepared:	September 26, 2017
Device Trade Name:	Cetus System
Common Name:	Phacofragmentation System
Classification Name:	Vitreous aspiration and cutting instrument, ophthalmic
Device product code:	HQE
Device Classification	21 CFR 886.4150
Predicate Device:	Laser Photolysis System, K993154

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Device Description:
The Cetus system is a 1064nm. pulsed, Nd:YAG Q-switched laser system used together with a sterile, single use laser probe and a Phaco machine. The system console has a digital touch screen and it is used in conjunction with the Cetus probe and a Phacoemulsification machine in the operating room. The probe converts the laser light energy into acoustic energy which is used to perform the fragmentation of the the crystalline lens and has integrated aspiration and irrigation functions.

Intended Use:
The Cetus Laser System is indicated for use in for phacofragmentation of the cataractous crystalline lens.

Substantial Equivalence:
The Cetus system have the same mechanism of action, same intended use and the same technological characteristics as the predicate device, the Laser Photolysis System (K993154). and that the minor differences should not raise concerns regarding safety and/ or effectiveness.

Comparison Table - Cetus system & Laser Photolysis System

Specification laser system	Subject Device	Predicate
510(k) #	K170183	K993154
Manufacturer	A.R.C. Laser	A.R.C. Laser
Indications for Use	Intended for use in phacofragmentation of the cataractous crystalline lens	Intended for use in phacofragmentation of the cataractous crystalline lens
Submission includes	Cetus laser system & Cetus probe only	Laser photolysis system, probe & phaco machine
Laser media	Nd:YAG	Nd:YAG
Mode of operation	Pulsed, Q-Switch	Pulsed, Q-Switch
Wavelength	1064 nm	1064 nm
Used in combination	with a probe and a Phaco machine	with a probe and a Phaco machine
Laser mechanism	Shockwave	Shockwave
Repetition rate	Max. 20Hz	Max. 20Hz
Laser Class	I	I
Pulse length	< 10 ns	< 10 ns
Mains supply	100V to 240V – 50/60 Hz	100V to 240V – 50/60 HZ
Cooling	Air, internal	Water, internal
Software	Integrated in system	From Phaco machine

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Comparison Table - Cetus system & Laser Photolysis System (Continuation)

Specification	Subject Device	Predicate
Laser beam delivery	Quartz optical fiber 300um with laser probe	Quartz optical fiber 300um with laser probe
Dimensions system	H 13,5 cm. (5,31 in.) X W 47,8 cm. (18,8 in.) X L 42,1 cm. (16,5 in.)	H 16 cm. (6,3 in.) X W 47 cm. (18,5 in.) X L 56 cm. (22 in.)
Display	Digital touch screen	External in Phaco machine
Weight	12 Kg. (26.4 pounds)	18 Kg. (39.6 pounds)

The Cetus system is a further development of its predicate (A.R.C. Laser Photolysis System, K993154). The predicate device (K993154) includes a laser system, a probe and a phaco machine. The current submission includes the laser system and the probe only. Additional minor differences between the subject and predicate systems include the cooling system (air vs. water), software (integrated vs. external), display, dimensions and weight as shown in the table above.

Non clinical Performance Data: Performance testing was conducted in order to demonstrate that the A.R.C. Cetus System is as safe and as effective as the cleared predicate device.

The Cetus system has been tested for Electrical Safety compliance to AAMI ANSI ES60601-1:2005(R) 2012 and A1:2012, for Laser Safety to IEC 60825-1:2007, for Electromagnetic Compatibility to IEC 60601-1-2:2007, Sterilization Validation to DIN EN ISO 11135-1:2014, Packaging Integrity to ASTM F1886/ F1886M-09:2013, Accelerated ageing of sterile barrier to ASTM F1980-07:2011, Sterile Packaging to DIN EN 868-5:2009, Microbial ranking of porous packaging materials to ASTM F1608-00:2009, Biological evaluation of EO residuals to DIN ISO 10993-7:2009 and Risk Management been conducted according to ISO 14971: 2007 + Am 2010.

According to the test results provided in this submission, we conclude that the Cetus system is as safe and effective as the predicate device.

Clinical Performance Data: None