JUN 2 9 2000

K993154

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510(k) Summary

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Daniel Hoefer
ARC Laser Corporation
1832 South 3850 West
Salt Lake City, UT 84104
(801) 972-1311, FAX (801) 972-5251

Name of Device:

Trade Name:
1. Pharo Ophthalmic Surgery System
2. Laser Photolysis System

Common Name:
1. Anterior and Posterior Segment surgical system
2. Phacofragmentation System

Classification name:
Phacofragmentation System, per 21 CFR 886.4670, Vitreous aspiration and cutting device per 21 CFR 886.4150, and Radio frequency Electrosurgery cautery device per 21 CFR 886.4100.

Product Code: HQC, HQE, MXO

Device Class: Class II

Predicate Devices:

The Pharo System is substantially equivalent to the following legally marketed devices: The Series 20000 Legacy (K952213) marketed by Alcon Laboratories, Inc., the Premiere Microsurgical System (K89478, K921460, K946227) marketed by Storz Instrument Company, and the Alcon Accuras, marketed by Alcon Laboratories, Inc.

The Laser Photolysis System is substantially equivalent to the following legally marketed devices: The Premiere Microsurgical System (K894278, K921460, K946227)marketed by

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Storz Instrument Company, and the Alcon Series 20000 Legacy marketed by Alcon Laboratories, Inc.

Description of Device:

The **Pharo Ophthalmic Surgery System** is a class II ophthalmic surgical system intended for use in anterior and/or posterior segment ocular surgery. Functions include Irrigation/Aspiration, Ultrasound phacoemulsification, Bipolar diathermy, pneumatic vitrectomy, pneumatic cutters and scissors, air and oil infusion system, and illumination.

The user interfaces include a foot controller and a touch screen control panel. The vaccuum system utilizes either a venturi or peristaltic pump system. Peripherals include the printer module, cart and trolley.

Accessories include an electric or manual infusion pole, cutters in several models, vitrectomes in several models, diathermy forceps and pencils in several models, ultrasound handpieces in either of two models, I/A handpieces in several models, fiber optic cables for illumination in several models, air exchange sets, tubing sets, and collection cassettes.

The **Laser Photolysis System** is intended for use in fragmentation of cataracts. The device consists of a laser console, which delivers energy by fiber optic via a disposable probe. The probe converts the laser light energy into acoustic energy, which is used to fragment the crystalline lens. The system is controlled by push buttons on the front panel and via footswitch. Irrigation/aspiration is provided by the Pharo system. Accessories include the laser photolysis probe and a dedicated irrigation handpiece.

Intended Use:

The Pharo Ophthalmic Surgery System is intended for use in anterior and posterior segment ocular surgery. The Laser Photolysis System is intended for use in fragmentation and removal of the cataractous crystalline lens.

Technological Characteristics/Device Comparison:

The **Pharo Opthalmcic Surgery System** is substantially equivalent to the 20000 Series Legacy marketed by Alcon Laboratories, Inc., the Premiere Microsurgical System manufactured by Storz Instrument Company and the Accuras

manufactured by Alcon Laboratories, Inc. Each is intended for anterior and posterior segment ophthalmic surgery. Each incorporates an infusion/aspiration system, ultrasound phacoemulsification via elecronically driven handpieces incorporating piezo-electric transducers, pneumatically driven vitrectomy attachments, and bipolar diathermy. Each allows programming by several surgeons. Re-usable, re-sterilizable attachments and accessories are available with each system. Both the Pharo and the Accuras utilize viscous fluid control systems for silicone oil infusion during posterior segment surgery.

The **Laser Photolysis System** utilizes a photoacoustic transducer to achieve phacofragmentation. An Nd:YAG laser system fires laser pulses of approximately 7 nanoseconds duration, which are deliverd by fiber optic to a titanium target in the disposable handpiece. Laser energy at a wavelength of 1064 nm is generated at energy levels of 6 to 10 millijoules per pulse, at repetion rates up to 20 Hz. Each pulse of laser energy causes plasma formation within the probe and results in the emission of shock waves from the opening in the probe tip. The shock wave energy is used to fragment the lens.

The laser energy emitted from the probe tip places the device in Class one, as defined in 21 CFR 1040.10(b)(5). No health risks have been identified for this level of radiation.

The Laser Photolysis System is substantially equivalent to Premiere Microsurgical System Marketed marketed by Storz Instrument Company and the Alcon 20000 Series Legacy marketed by Alcon Laboratories, Inc. Each device is intended for fragmentation and removal of the cataractous crystalline lens. Each device uses acoustic shock waves to break up the lens, then aspirates the material through the same probe. The materials, warnings, side effects, and methods are all substantially the same.

Conclusion:

The Pharo Ophthalmic Surgical System is substantially equivalent to the 20000 Series Legacy marketed by Alcon Laboratories, Inc., the Accuras marketed by Alcon Laboratores, and the Premiere Microsurgical System marketed by Storz Instrument Company, already legally marketed. The materials, design, intended use, surgical methods, and labeling are all substantially the same, and no new questions of Safety and Effectiveness arise.

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The Laser Photolysis System is substantially equivalent to the 20000 Series Legacy marketed by Alcon Laboratories, Inc. and the Premiere Microsurgical System marketed by Storz Instrument Company, already legally marketed. The materials, intended use, surgical methods, and labeling are all substantially the same. The technological difference in the Laser Photolysis System does not raise new questions of Safety and Effectiveness, and/or equivalence is demonstrated by performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2000

Mr. Daniel Hoefer
Regulatory Affairs Manager
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, Utah 84120

Re: K993154
Trade Name: Pharo Ophthalmic Surgery System
Laser Photolysis System
Regulatory Class: II
Product Code: GEX, HQC
Dated: April 7, 2000
Received: April 10, 2000

Dear Mr. Hoefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K993154

Device Name: 1. ~~LASIK~~ Photolysis System
2. Pharo Ophthalmic Surgery System

Indications For Use:

1. The Laser Photolysis System is indicated for use in phacofragmentation of the cataractous crystalline lens.

2. The Pharo Ophthalmic Surgery System is indicated for use in phacofragmentation of the cataractous crystalline lens, and anterior and posterior ophthalmic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993154

Prescription Use X **OR Over-The-Counter Use** ____
(Per 21 CFR 801.109)

(Optional Format