SEP 29 2004

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510K Summary

WaveLight®

510(k) Summary of Safety and Effectiveness – ARION Device

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Contact Person:	Alexander Popp WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Summary Preparation Date:	July 30, 2004

2. **Names**

Device Name:	ARION
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. **Predicate Devices**

The ARION laser system is substantially equivalent to the Light Age Epicare Model LPX (K983977), the Sharplan EpiTouch 5000 Alexandrite laser system (K971874), the Sharplan EpiTouch 5000 Alexandrite laser system (K973354), the Candela Gentlelase family of laser systems (K024260), the Candela Gentlelase family of laser systems (K024335), the Candela Gentlelase GL (K994260), the Cynosure Apogee-Tks II (K031488), and the Cynosure Apogee-Tks (K992757).

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510(k) Summary of Safety and Effectiveness – ARION Device

4. Device Description

The ARION is a 755 nm solid-state long-pulsed Alexandrite laser system. The beam is directed to the treatment area by a transmission system which is connected to the laser device. The EPI Zoom Ax transmission system consists of a hand piece attachment with a firmly attached fiber and a hand piece. The hand piece insert can be moved within the hand piece and determine the application and parameter ranges. The hand piece insert in the transmission system hand piece can snap into various positions. The number located closest to the hand piece indicates the spot diameter on the skin in mm (spot sizes: 6/8/10/12/14 mm). The integrated hand piece detection feature automatically shows the selected spot diameter on the laser display. The parameter range is also automatically adjusted for the corresponding range. The MedArt 928 scanner for ARION consists of a scanner with a connected transmission system and a spacer with a 8, 9, 10 and 12 mm spot size. The spacer determines the spot diameter on the skin and therefore the parameter range of the configurable energy densities as well. The spacers are inserted into the scanner as shown below and must be inserted into the scanner up to the limit stop position. The spacers now automatically sets a spot diameter of 8, 9, 10, and 12 mm on the skin; this is also shown automatically on the laser display. The parameter range is also automatically adjusted for the corresponding range. For epidermal cooling can be a cooling device adapted to the handpiece / scanner.

5. Indications for Use
The ARION laser system is indicated:

1. The ARION Alexandrite Laser is intended for use in dermatology for hair removal for skin types Fitzpatrick I - IV.

6. Performance Data
None presented.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2004

WaveLight Laser Technologie, AG
c/o Mr. William J. Sammons
Conformity Assessment Services
Underwriters Laboratories, Inc
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, North Carolina 27709

Re: K042474
Trade/Device Name: ARION
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 31, 2004
Received: September 13, 2001

Dear Mr. Sammons:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Indication for use

WaveLight®

510 (k) Indication for Use

510(k) Number (if known) K042474

Device Name ARION

Indications for Use:

1. The ARION Alexandrite Laser is intended for use in dermatology for hair removal for skin types Fitzpatrick I - IV.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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