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510(K) Summary

AUG 2 7 2009

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Date Summary Prepared:	August 26th, 2009
Device Trade Name:	Minisilk_FT
Common Name:	Intense Pulsed Light System
Classification Name:	Powered light based non-laser surgical instrument with thermal effect ONF 21 CFR 878.4810
Equivalent Devices:	Cynosure Photolight PL - K031258
Device Description:	The Minisilk_FT is a pulsed light system having a Xenon flashlamp located in the handpieces. It is a light source emitting in the wavelength range 500-1200 nm. Emission activation is by footswitch. Overall weight of the system is 16 kg, and the size is 22x37x45 cm (H x W x D). Electrical requirement is: 115 VAC, 10A, 50-60 Hz, single phase.
Indications for Use:	The Minisilk_FT pulsed light device is indicated for permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels and treatment of benign pigmented lesions.
Comparison:	The Minisilk_FT system has the same indications for use, the same principle of operation, and essentially the same wavelength range and pulse energy range as the predicate device.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Minisilk_FT is another safe and effective device for permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels and treatment of benign pigmented lesions.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

El. En. S.p.A.
% Ms. Andrea Tozzi
Quality System Manager & Official Correspondent
Viaa Baldanzese, 17
50041 Calenzano (FI) – Italy

AUG 2 7 2009

Re: K082040
Trade/Device Name: Minisilk_FT
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: ONF
Dated: August 5, 2009
Received: August 10, 2009

Dear Mr. Tozzi:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K082040

Device Name: Minisilk_FT

Indications For Use:

The Minisilk_FT pulsed light device is indicated for permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels and treatment of benign pigmented lesions.

Prescriptive Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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