13. 510(k) Summary of Safety And Effectiveness for Model LAD-08

13.1 Submitter Information

FEB 2 0 2004

Norwood Abbey Limited.
63 Wells Road
Chelsea Heights Victoria 3196
Australia

Contact Person: Paul Clark
Telephone No.: +61-3-9782 7308
Fax: +61-3-9782 7334

13.2 Device Name

Classification Name: Laser surgical instrument for general and plastic surgery and in dermatology

Proprietary Name: LAD, model LAD-08

13.3 Predicate Devices

LAD-01/06

13.4 Description of the Device

The Norwood Abbey Model LAD-08 is a portable, handheld, battery powered Er:YAG laser. The radiant energy produced by this laser has a wavelength of 2.94 μm and a beam diameter or spot-size of 6 mm at the treatment site. The radiation delivered by the device is sufficient to remove the stratum corneum of skin exposed to the treatment.

13.5 Intended Use

The intended use of the LAD-08 is for ablation of the outer layer of the skin prior to the application of OTC topical 4% lidocaine cream, for local dermal anesthesia.

13.6 Clinical Studies

No additional studies have been performed on the LAD-08.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Mr. Paul Clark
Quality and Regulatory Affairs Manager
Norwood Abbey Limited
63 Wells Road
Chelsea Heights Victoria 3196
Australia

Re: K033962
Trade/Device Name: Epiture™ Easytouch, Model LAD-08
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: December 18, 2003
Received: December 22, 2003

Dear Mr. Clark:

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.

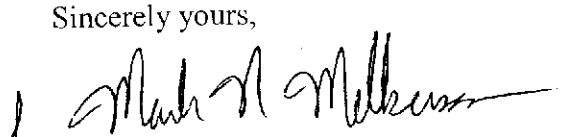
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

3.2 Statement of Intended Use

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510(k) Number (if known): K033962

Device Name: Epiture™ Easytouch , Model LAD-08

Indications for Use:

LAD-08 is indicated for ablation of the outer layer of the skin prior to the application of OTC topical 4% lidocaine cream, for local dermal anesthesia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The Counter Use ☐
(Per 21 CFR 801.109)

for Mark N Milhem

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

510(k) Number K033962