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SECTION 8

510(k) SUMMARY K023899

This 510(k) summary of safety and effectiveness for Norseld Dual Yellow D10B laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Norseld Pty., Ltd.

Address: 9 Claxton St
Adelaide
South Australia 5000

Manufacturer: Norseld Pty, Ltd.
9 Claxton St
Adelaide
South Australia 5000

Contact Person: Mr. Peter Davis
Managing Director

Telephone: +618 82319000

Preparation Date: November 2002
(of the Summary)

Device Name: Dual Yellow D10B Laser

Common Name: Laser surgical device

Classification: Laser surgical device
Class II medical device
21 CFR 878.4810

Product Code: GEX
Panel: 79

Predicate devices: YellowStar Laser System

Device description: The Norseld Dual Yellow D10B Laser is a copper bromide laser which emits it energy at 511 and 578 nm. The device consists of an cabinet, fiber optic delivery system, and a user/software interface.

Indications: The Dual Yellow Laser is intended for treatment of vascular and pigmented lesions.

The Dual Yellow Laser is a restricted device and is labeled:

"CAUTION: Federal (US) law restricts this device to sale to or use by licensed professionals."

Performance Data: The Dual Yellow D10B Laser has the same specifications and indications for use as the YellowStar Laser (K013940) which is also manufactured by Norseld, Pty., Ltd.

CONCLUSION: Based on the information in the notification Norseld Pty., Ltd. believes that Dual Yellow D10B Laser is substantially equivalent to (i.e., the same as) the YellowStar Laser System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Mr. Roger Barnes
Regulatory Consultant
Norseld Pty., Ltd.
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K023899
Trade Name: Dual Yellow D10BLaser
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: November 20, 2002
Received: November 22, 2002

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket 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) 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,

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

SECTION 6

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023899

Device Name: Norseld Pty., Ltd. Dual Yellow D10B Laser

Indications for Use Statement:

The Dual Yellow Laser is intended for the treatment of vascular and pigmented lesions.

The Dual Yellow Laser is also labeled as a restricted device:

"CAUTION: Federal (US) law restricts this device to sale to or use by licensed professionals."

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

Concurrence of CDRH, Office of Device Evaluation

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023899