510(k) Summary

Submitter:

DIROS TECHNOLOGY INC
232 Hood Road
Markham, ON
L3R3K8, Canada

JAN 22 2010

Contact:

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Date: September 28, 2009

Trade Name: Diros OWL™ URF-3AP(ML)

Common Name: OWL Radiofrequency System

Classification Name: Generator, Lesion, Radiofrequency

Regulatory Class: II

Product Code: GXD

Regulation Number: 882.4400

REGISTRATION NO: 8043398

OWNER/OPERATOR NO: 9001301

Predicate Devices:

We are making the claim that the DIROS OWL URF-3AP(ML) which is the URF-3AP with the multiple lesion adaptor accessory MLA-4 is substantially equivalent to the predicated devices listed in the chart below.

LEGALLY MARKETED PREDICATE DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
OWL URF-3AP	DIROS TECHNOLOGY INC	Class II/GXD	K062758
PMG-115	BAYLIS MEDICAL COMPANY	Class II/GXD	K072478

The rationale of declaring the DIROS OWL™ URF-3AP(ML) is substantially equivalent to the above 2 predicate devices is based on the following:

- ✓ Same Indications for use: All systems provide treatments by making heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. All systems are using the same fundamental scientific technology.
- ✓ Similar key design technical characteristics- Pain relief is achieved by the controlled heating of the area surrounding the electrode tip. A thermosensor in the probe is used to control tissue temperature. Impedance values are displayed to guard against unsafe conditions. The PMG-115 includes an accessory that provides up to four simultaneous lesions.
- ✓ Same/similar components for treatment and measurement.
- ✓ Similar size, power source, and performance

Description:

The Diros OWL™ radiofrequency generator URF-3AP(ML) is used by qualified medical personnel to make heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. The lesions are ablative in order to be therapeutic; i.e. the destruction of a small portion of the thalamus within the brain interferes with the motor pathway causing the tremor of Parkinson's disease, thereby relieving the tremor; or the destruction of the facet joint nerves in the lumbar vertebrae to block pain transmission by these nerves and thereby relieve certain types of low back pain.

The URF-3AP(ML) supplies up to 50 Watts of Radio Frequency energy at 481kHz under power or temperature control while continuously monitoring and displaying actual power delivered, measured probe temperature, time of power duration, and measured impedance. This 50W RF source can be directed to one of four channels, one at a time, to create simultaneously up to four lesions.

When used with monopolar probes, the system also delivers low-frequency stimulus pulses in either voltage or current controlled modes.

Indications for Use:

The DIROS OWL™ URF-3AP(ML) SYSTEM is intended for the following:

1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or
2. radiofrequency heat lesion procedures for the relief of pain

The MLA-4 Multi-Lesion adaptor is not intended for use in brain surgery.

Summary of Performance Testing:

A risk analysis identifying potential hazards and documenting mitigations of the hazards has been developed and applied as part of the DIROS OWL ™URF-3AP(ML) product development cycle. The risk analysis is based on EN 1441/ISO14971 - Risk Analysis for Medical Devices.

Testing was performed to validate the functional performance of the DIROS system. In particular, specific performance testing of the software was performed to show that the performance was met.

The DIROS OWL™ URF-3AP(ML) has been subjected to performance testing to applicable safety, electrical, mechanical, EMC standards. The DIROS OWL URF-3AP(ML) system has been evaluated and has passed all mechanical and electrical safety according to CSA International. Standards that were investigated are: IEC 60601-1, UL 60601-1 and CAN/CSA C22.2No.601.1-M90 certified, IEC 60601-1-2 and FCC 15 Subpart B. The URF-3AP(ML) has also been evaluated and satisfies the requirements to IEC 60601-2-2 Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment.

Conclusion:

As stated above, DIROS TECHNOLOGY INC.'s conclusion is that the DIROS OWL™ URF-3AP(ML) is safe and effective and complies with the appropriate medical standards and is substantially equivalent to the above identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Diros Technology, Inc.
c/o Mr. George Darmos
President
232 Hood Rd.
Markham, Ontario
Canada L3R 3K8

JAN 2 2 2010

Re: K093185
Trade/Device Name: DIROS OWL™ URF-3AP(ML)
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: II
Product Code: GXD
Dated: December 2, 2009
Received: December 7, 2009

Dear Mr. Darmos:

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

Jessica Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093185

Device Name: DIROS OWL™ URF-3AP(ML)

Indications for Use:

The DIROS OWL™ URF-3AP(ML) LESION GENERATOR is intended for the following:

1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or
2. radiofrequency heat lesion procedures for the relief of pain

The MLA-4 Multi-Lesion adaptor is not intended for use in brain surgery.

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

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093185