K110593

MAY - 5 2011

Special 510(k) SUMMARY

Submitter Information

Company Name:	Diros Technology Inc.
Company Address:	232 Hood Road Markham, ON L3R 3K8
Company Phone:	(905) 415-3440
Company Fax:	(905) 415-0667
Contact Person:	George Darmos, President

Device Identification

Trade/Proprietary Name:	OWL Sterile Single Use RF Probes
Classification:	II
Classification Name:	Probe, Radiofrequency Lesion
Product Code:	GXI
Regulation Number:	882.4725

Devices to which Submitted device is a modification

OWL Reusable RF Probes:	K010202

Device Description

The Diros OWL RF Probe/Temperature Sensor is a modification of the previously 510(k) cleared OWL Reusable RF Probes. The modification includes the change of the device from reusable to sterile and single use as well as the option to include a thermocouple in place of a thermistor for temperature measurement.

Intended Use

The OWL Sterile Single use R.F. Probe is intended for use in Radio-Frequency Heat Lesion procedures for relief of pain.

Substantial Equivalence

The OWL Single Use RF Probes consist of a set of temperature measurement probes at different lengths. These probes can be inserted in RF cannulae to measure the temperature at the point of RF delivery. The probes are modifications to the set of

reusable Diros probes approved in K010202, and any differences between the two probe sets do not affect safety or efficacy.

To demonstrate substantial equivalence, dimensional comparison, and comparison testing has been done between the cleared reusable probes and the disposable probes. Table 1 below compares the Diros single use probes to the reusable probes.

Characteristic	**Diros Disposable Probes**	**Diros Reusable Probes K010202**	**Comments**
Intended Use	The OWL Sterile Single use R.F. Probe/Temperature Sensor is intended for use in Radio-Frequency Heat Lesionprocedures for relief of pain.	The OWL R.F. Probe/Temperature Sensor is intended for use in Radio-Frequency Heat Lesion procedures for relief of pain.	Intended use is identical with the exception of single use characteristic discussed below.
Diameter	25AWG and 27 AWG	25AWG	-
Lengths Available (Cannulae length to be used with)	65.8mm (5cm) 116.5mm (10cm) 161mm (15cm) 194mm (20cm)	65.8mm (5cm) 116.5mm (10cm) 161mm (15cm)	Length of probe is determined by length of cannula to ensure probe measures temperature at lesion site.
Temperature measurement devices available	Thermistor Thermocouple	Thermistor only	Temperature accuracy of thermocouple has been demonstrated through comparison testing with predicate to be as accurate as Thermistor type and is provided in section 18 (Bench Testing)
Single Use	Yes	Reusable	Single use characteristic does not affect safety and efficacy. Sterilization and packaging validation confirm that single use device can be used safely out of package.

CONCLUSIONS

The differences between the OWL Reusable RF Probes and OWL Disposable RF Probes do not affected the intended use or performance characteristics, and do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 5 2011

Diros Technology Inc.
c/o Mr. George Darmos
President
232 Hood Road
Markham, Ontario L3R3K8, Canada

Re: K110593
Trade/Device Name: Diros OWL Single Use Disposable RF Probes/Temperature Sensors (D466, D467)
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: Class II
Product Code: GXI
Dated: April 6, 2011
Received: April 7, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia 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 Statement

510(k) Number (if known):

Device Name: Diros OWL Single Use Disposable RF Probes/Temperature Sensors (D466, D467)

Indications for Use:

The OWL Sterile Single Use Disposable R.F. Probe/Temperature Sensor is intended for use in Radio-Frequency Heat Lesion procedures for relief of pain.

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 K110593