DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 30, 2014

Diros Technology, Inc.
George Darmos
President
120 Gibson Drive
Markham, ON
L3R 2Z3
Canada

Re: K141586
Trade/Device Name: Diros OWL Sterile Single Use R.F. Insulated Cannulae, Models 466 and DHC
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: November 28, 2014
Received: December 1, 2014

Dear George 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141586

Device Name
Diros OWL Single Use 16 Gauge Disposable Cannulae (466, DHC)

Indications for Use *(Describe)*
The Diros OWL cannulae are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SUBMITTER INFORMATION

Company Name:	Diros Technology Inc.
Company Address:	120 Gibson Drive Markham, ON L3R 2Z3 Canada
Company Phone:	(905) 415-3440
Company Fax:	(905) 415-0667
Contact Person:	George Darmos, President
Date Prepared:	February 10, 2015

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Diros OWL Sterile Single Use R.F. Insulated Cannulae
Model:	466 and DHC
Classification:	II
Generic Device Name:	Cannulae
Classification Name:	Probe, Radiofrequency Lesion
Product Code:	GXI
Regulation Number:	21 CFR 882.4725

PREDICATE DEVICES

Diros RF Cannula:	K102566
Cosman 16Ga Cannula:	K060799

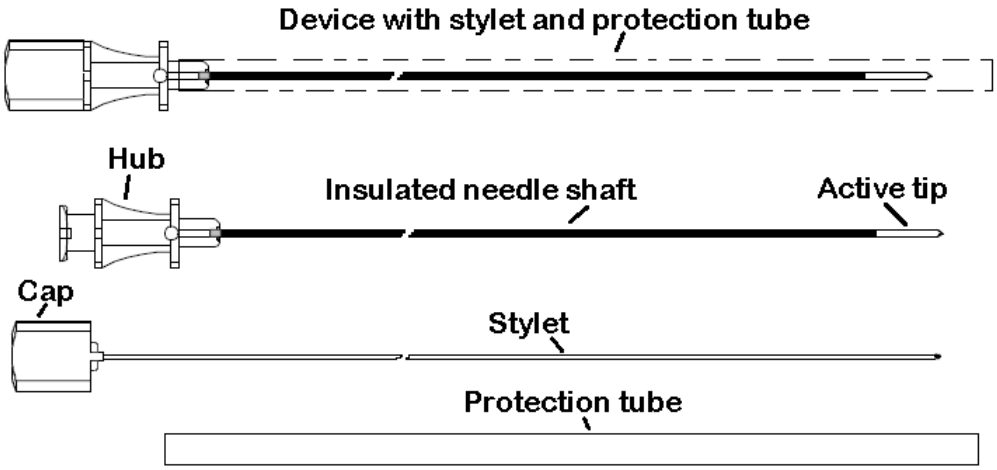
PRIOR SUBMISSION

There was no prior submission for the Diros OWL Sterile Single Use Disposable 16Ga Cannulae models 466, DHC.

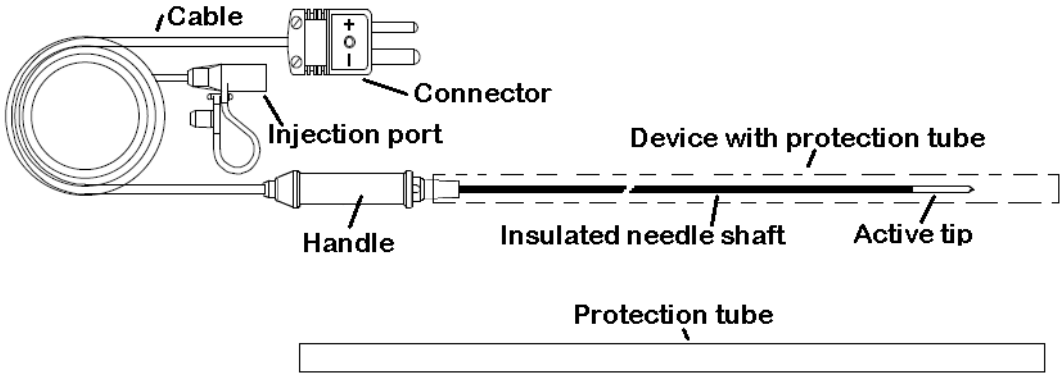
DEVICE DESCRIPTION

The Diros OWL Sterile Single Use Disposable 16Ga Cannulae models 466, DHC are identical in construction, materials, energy source and intended use to predicate devices. They are single use disposable devices to be used with the Diros OWL RF Generators.

The 466 series 16Ga cannula consists of a sharp insulated needle with a partially uninsulated part of the shaft near the tip. Needle shaft is permanently attached to the hub that is used as a handle and the fluid injection port. The device also has a detachable stylet with cap. The device is supplied with a protection tube that protects the needle from damage. The protection tube is detached from the device prior to use.



The DHC series 16Ga cannula consists of a sharp insulated needle with a partially uninsulated part of the shaft near the tip. The Needle shaft is permanently attached to the handle. The handle also is permanently attached to the thermocouple probe, cable (with connector) and injection port. The Thermocouple probe is used to deliver the RF energy from the generator and measure the needle tip temperature. The injection port is used for fluid injection. The device is supplied with a protection tube that protects the needle from damage. The protection tube is detached from the device prior to use.



MATERIALS

Materials used in 466 series devices

Component	Material	Body Contact (Y/N)
Shaft	304 Stainless Steel	Y
Insulation	Polyester	Y
Hub	Polycarbonate	Indirect through injected fluid
Adhesive	UV Adhesive	N
Protection tube	LDPE	N

Materials used in DHC series devices

Component	Material	Body Contact (Y/N)
Shaft	304 Stainless Steel	Y
Insulation	Polyester	Y
Handle	Polycarbonate	Indirect through injected fluid
Adhesive	UV Adhesive	N
Cable	Silicone	N
Connector	Nylon	N
Thermocouple	Copper/Constantan	N
Injection Port	Tubing: Vinyl Cap: PEBD Female Luer: PVC	Indirect through injected fluid
Protection tube	LDPE	N

ENERGY TYPE

The devices are using RF energy supplied by Diros OWL RF generators. The Diros OWL RF Generator applies temperature-controlled, radio frequency (RF) energy into targeted nerve tissue near the active tip of device. This energy disables the nerve tissue's ability to conduct electrical signals. Pain relief is achieved by creating lesions on pain-conducting nerve fibers or tissue.

TECHNOLOGICAL FEATURES

The 466 series cannulae consist of a sharp insulated needle with partially uninsulated part of the shaft near the tip. The needle also has a removable stylet with cap. The tip of the cannula is placed near the target nerve and the stylet is then removed from the device. Then a separate RF probe is introduced into the cannulae to perform the procedure, which may include the stimulation and RF lesion. The same cannula is used (with stylet and probe withdrawn) to administer the injections when it is required.

The DHC series cannulae consist of a sharp insulated needle with partially uninsulated part of the shaft near the tip. The tip of the DHC cannula is placed near the target nerve to perform the procedure, which may include the stimulation and RF lesion. There is no separate RF probe required to perform the procedure, because the DHC series devices have the built in probes. The injection port of the device is used to administer the injections when it is required.

INDICATIONS FOR USE

The Diros OWL cannulae are injection needles which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. A nerve is localized either by using electrostimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic solution or a radiofrequency lesion may be made.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The 16G cannulae 466 and DHC series that are included in this submission are identical to predicate devices in the following aspects listed in the table below:

The technological principle for the subject and the predicate devices is identical. Both devices are using the conductive metal shaft to deliver the RF energy to target tissue. Both devices are creating the lesion only in the tissue surrounding the bare tip (uninsulated part) of the device. The size of the lesion is ruled by the size of the bare tip, temperature and the duration of the procedure.

Technological elements that are the same between the subject and the predicate devices;

- Indications for use
- Where used
- Energy used
- Design features
- Performance
- Standards applicable
- Materials used
- Biocompatibility
- Compatibility with other devices
- Sterility
- Electrical safety
- Mechanical safety

Technological elements that are different between the subject and the predicate devices;

- The 16Ga cannulae included in this submission are larger gauge cannula that extends the range of cannula cleared in K102566 (18Ga-22Ga).
  In addition, equivalent 16Ga cannula are currently marketed by Cosman Medical and cleared under K060799.

SUMMARY OF NONCLINICAL TESTING (PERFORMANCE DATA)

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

- Cytotoxicity (same materials, same report as for predicate device)
- Sensitization (same materials, same report as for predicate device)
- Irritation (same materials, same report as for predicate device)
- Systemic toxicity (same materials, same report as for predicate device)
- Pyrogen Testing

Electrical safety and electromagnetic compatibility (EMC)

- Electrical safety and High Frequency testing;

- EMC (Emissions and Immunity) testing is the same as for predicate device

Note: Cannulae are the same length as were tested. All cables and generators used in test are identical to those indicated

Mechanical testing

- Mechanical testing is provided in the testing;
  - ISO 9626 Stainless steel needle tubing for the manufacture of medical devices
  - ISO 7864 Bond force is tested between hub/handle and shaft
  - ISO 6009 The nominal O.D. of needle is identified by color coding to standard
  - ISO 7864 Needle Geometry
  - ISO 594-1 Male 6% (Luer) conical taper
  - ISO 594-2 Female 6 % (Luer) conical lock fittings
  - ISO 594-1 Separation force is tested between conical fitting assembly
  - Dimensional Testing
  - Anchorage test – cable and connector

Performance testing

- Performance testing;
  - Compatibility between probes, cannulae is verified by measurements and performance testing
  - Temperature accuracy, Accuracy verified by measurements and performance testing
  - Measured RF Lesion Size in Tissue Model

All nonclinical testing performed on new devices are identical to testing performed on Diros predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing are demonstrating the compliance to the standards and matching the performance of new devices to the predicate devices. The single difference between the new and predicate Diros devices is the diameter of the cannulae increasing from (the largest) 18Ga to 16Ga. Testing has demonstrated identical performance between the new Diros and predicate Diros devices with a single exception

of the size of the lesion created. The larger lesion is a completely expected result, because the new devices are larger in diameter and intended to create respectively larger lesions. The lesion size of the new devices should be identical to marketed by Cosman Medical (used as predicate device in this submission) for the following reasons:

Identical diameter of active tip - 16Ga
Identical length of active tips - 6mm or 10mm
Identical energy type - RF energy
Identical intended use

CONCLUSIONS

The predicate devices were cleared based on the results of non-clinical data. Subject and predicate device performance data were compared to support the safety of the subject devices and demonstrate that the Diros OWL 16Ga Model 466 and DHC Cannulae should perform as intended in the specified use conditions.