DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 30, 2015

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

Re: K150371
Trade/Device Name: Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: July 21, 2015
Received: July 22, 2015

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

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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

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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)*
K150371

Device Name
Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH

Indications for Use *(Describe)*
Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH 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)

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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:	July 28, 2015

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH
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, K141586
Biomerics. LLC NIMBUS Cannula:	K121773

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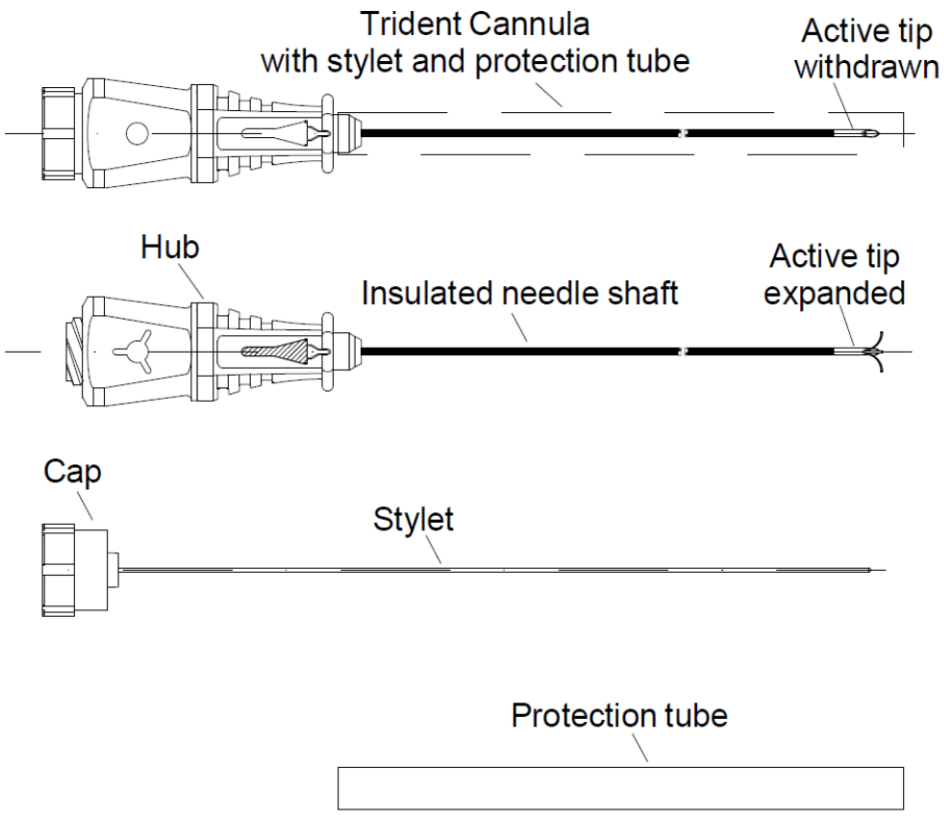
DEVICE DESCRIPTION

The Diros OWL Sterile Single Use Trident™ RF Cannulae DTR and DTRH models are very similar in construction, materials, energy source and intended use to predicate devices of 466 and DHC. They are single use disposable devices to be used with the Diros OWL RF Generators.

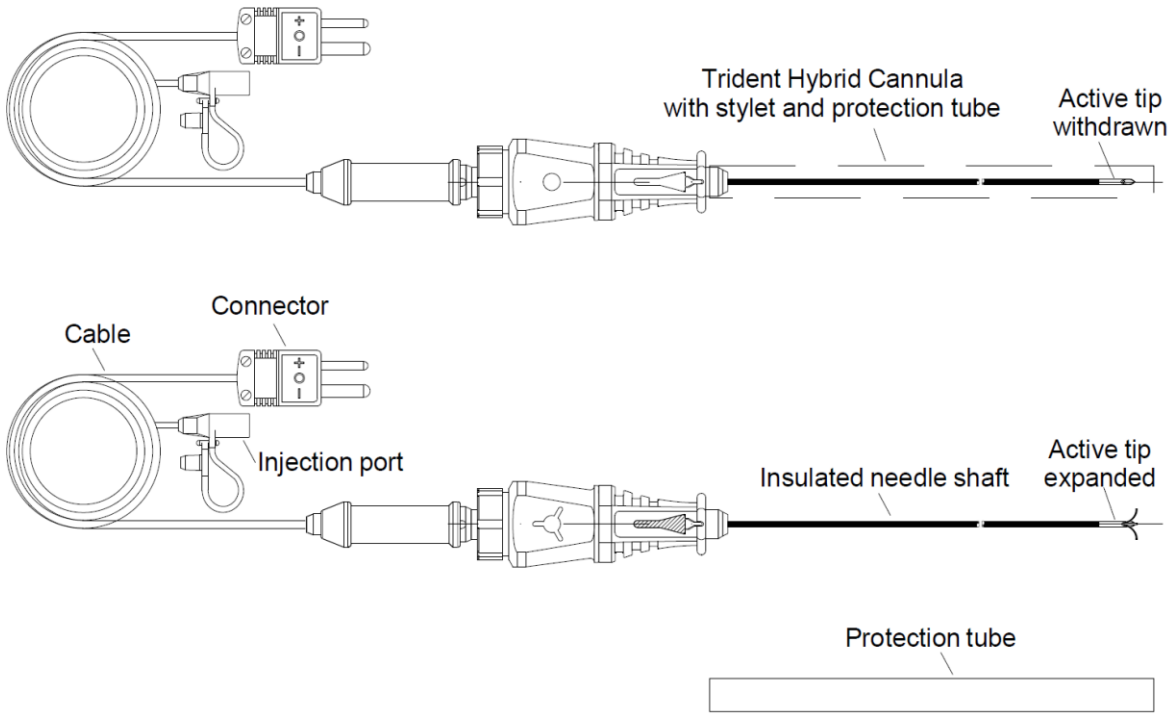
Sterile Single Use Trident™ RF Cannulae model DTR

The DTR device 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 active tip has expandable tines, which are normally withdrawn and only expanded once the device is placed in desired position. 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.



Sterile Single Use Trident™ RF Hybrid Cannulae model DTRH

The DRTH device 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 active tip has expandable tines, which are normally withdrawn and only expanded once the device is placed in desired position. 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 Trident™ RF Cannulae (DTR) devices

Component	Material	Body Contact (Y/N)
Shaft	304 Stainless Steel	Y
Insulation	Polyester	Y
Tines	Nitinol	Y
Hub	Polycarbonate	Indirect through injected fluid
Handle/Actuator	ABS	N
Protection tube	LDPE	N

Materials used in Trident™ RF Hybrid Cannulae (DTRH) devices

Component	Material	Body Contact (Y/N)
Shaft	304 Stainless Steel	Y
Insulation	Polyester	Y
Tines	Nitinol	Y
Handle	Polycarbonate	Indirect through injected fluid
Injection Port	LDPE/EVA/PVC Multilayer Tubing (DEHP free)	Indirect through injected fluid
Handle/Actuator	ABS	N
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 DTR 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 DTRH series cannulae consist of a sharp insulated needle with partially uninsulated part of the shaft near the tip. The tip of the DTRH 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 DTRH series devices have the built in probes. The injection port of the device is used to administer the injections when it is required.

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INDICATIONS FOR USE

The Diros OWL Sterile Single Use Trident™ R.F. Insulated Cannulae Models DTR and DTRH 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 Diros OWL Sterile Single Use Trident™ RF Cannulae DTR and DTRH series that are included in this submission are identical to predicate devices 466 and DHC in the following aspects listed in the table below:

Characteristic	Comments	Comparison
Intended Use/ Indications for use	Devices are indicated for RF heat lesion procedures.	same
Where used	Devices are used in clinical setting by trained professionals.	same
Energy used	Devices are using the RF energy	same
Design features	Insulated needle with partially uninsulated part of the shaft near the tip.	same
Performance	Devices are performing identically in the same settings. Devices are using the conductive metal shaft to deliver the RF energy to target tissue.	same
Standards applicable	Devices are subjected and in compliance with the same standards.	same
Material Shaft	Stainless Steel 304	same
Material Shaft Insulation	Polyester	same
Biocompatibility	Devices are classified and in compliance with the same ISO 10993 standards.	same
Compatibility with other devices	Devices are performing identically in conjunction with the same equipment.	same
Electrical safety	Devices are in compliance with the same IEC 60101-X-X standards.	same
Mechanical safety	Devices are similar in design and construction. Devices were subjected and passed to the same mechanical testing.	same
Sterility	Devices supplied “STERILE”	same
Packaging	Device individually packaged and sealed in a single use Tyvek/Poly pouch	same
Sterilization	Both devices are EtO sterilized	same
Material Tines	“Trident” device- Nitinol “Nimbus” device- unknown	different

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

The DTR and DTRH included in this submission have an expandable tip, equivalent to NIMBUS that is currently marketed by Biomerics. LLC and cleared under K121773.

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SUMMARY OF NONCLINICAL TESTING (PERFORMANCE DATA)

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 shape of the lesion with tines expanded. The size of the lesion is comparable to that is created by NIMBUS device when 17Ga 10mm devices are compared.
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing Patient contact materials are classified as tissue/bone/dentin < 24hours and tested for compliance to applicable ISO 10993 standards. New device is similar in classification and the materials used in construction as a predicate device therefore the same – reports are used for Cytotoxicity, Sensitization, Irritation, Systemic toxicity as for a predicate device. Additional testing per ISO 10993-7 is performed to evaluate the new device for EtO residuals.		
Test	**Test method Summary**	**Results**
Cytotoxicity	ISO 10993-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed “Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity.” (same materials, same report as for predicate device)
Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10: Tests for irritation and skin sensitization	Passed “The article did not elicit a sensitization response under the conditions the of test assay.” (same materials, same report as for predicate device)
Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10: Tests for irritation and skin sensitization	Passed “The article considered a non-irritant under the conditions of the test assay.” (same materials, same report as for predicate device)
Systemic toxicity	ISO 10993-11 Biological evaluation of medical devices –Part 11: Tests for systemic toxicity	Passed “The article meets the requirements for the absence of pyrogens as specified under the conditions of the test assay.” (same materials, same report as for predicate device)
EtO residuals	ISO 10993-7 Biological evaluation of medical devices –Part 7: Ethylene oxide sterilization residuals	Passed “The levels of the EO residuals are below the specified limits in ISO 10993-7 for the particular contact types devices.” EtO residuals testing report

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Electrical safety testing The new device is similar in size, materials, construction and used with the same equipment as a predicate device, therefore the same- IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 test reports are applicable as for a predicate device. Additional testing also performed as a part of IEC 60601-2-2 for high frequency surgical accessories.		
Test	**Test method Summary**	**Results**
Electrical safety	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	Passed (same as for predicate device)
High frequency surgical equipment	IEC 60601-2-2 Medical electrical equipment Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Passed (same as for predicate device)
High frequency surgical accessories	IEC 60601-2-2 Medical electrical equipment Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Passed HF Accessory - Leakage current (201.8.8.3.102) HF Accessory - Dielectric Strength (201.8.8.3.103) (201.8.8.3.104)
EMC	IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility	Passed (same as for predicate device)

Mechanical testing The new device and a predicate device are similar in size, materials, construction and used with the same equipment, therefore the same tests were executed and passed successfully.		
Test	**Test method Summary**	**Results**
Stainless Tube dimensions, surface and mechanical properties compliance	ISO 9626 Stainless steel needle tubing for the manufacture of medical devices	Pass CofC
Bond force is tested between hub/handle, shaft, stylet and tines	ISO 7864 Sterile hypodermic needles for single use	Pass Pull testing with an axial force is applied in a direction of the separation of the parts; Hub/Handle – Needle Shaft Cap– Stylet Hub/Handle –Tines Shaft Hub/Handle –Tines
Needle Geometry	ISO 7864 Sterile hypodermic needles for single use	Pass Triple bevel tip per drawing
The nominal O.D. of needle is identified by color coding to standard	ISO 6009 Hypodermic needles for single use – Colour coding for identification	Pass Visual inspection
Male 6% (Luer) conical taper	ISO 594-1 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements	Pass Gauging (5.1)
Female 6 % (Luer) conical lock fittings	ISO 594-2 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings	Pass Liquid leakage - (5.2) Air leakage - (5.3) Separation force - (5.4) Unscrewing torque - (5.5) Resistance to overriding - (5.7) Stress cracking - (5.8)
Dimensional measurement	Drawings	Pass Measured per drawing
Anchorage test – cable and connector	IEC 60601-2-2 Medical electrical equipment Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Pass HF Accessory - Connection cable anchorage test (201.8.10.4.2)

Performance testing The new and the predicate device will be used in the same setting and for the same reason. Testing executed on a new device and the predicate device, demonstrated similar performance under the same conditions.		
Test	**Test method Summary**	**Results**
Compatibility between probes, cannulae	Verified by dimensional measurements and performance testing	Pass Cannulae to probe length matching Impedance measurement Energy coupling
Temperature accuracy,	Accuracy verified by measurements and performance testing	Pass Temperature coupling Temperature accuracy
Lesion	Measured RF Lesion Size in Tissue Model	Pass Lesion size Lesion shape

CONCLUSIONS

The predicate devices were cleared based on the results of non-clinical data. Subject device has a similar safety profile when compared to the predicate devices and demonstrate that the Diros OWL Sterile Single Use Trident™ RF Cannulae DTR and DTRH series should perform as intended in the specified use conditions

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