K103128

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510k Summary

FEB 2 3 2011

Submitter:	Cadwell Laboratories, Inc.
Contact Person:	Chris Bolkan Safety / Regulatory Specialist Cadwell Laboratories, Inc. 909 N. Kellogg Street Kennewick, Washington 99336
Date Prepared:	January 25, 2011
Trade Name:	Cadwell Disposable Stimulator Probes
Classification Name And Number:	Class II, 21 CFR 874.1820
Product Code:	GXZ, ETN
Classification Panel:	Ear, Nose and Throat
Predicate Device:	Technomed ..... K050325 Technomed ..... K063729 Axon ..... K062996 XOMED ..... K992869 XLTEK ..... K062549 Medtronic Xomed ..... K031003 Medtronic Xomed K014165
Substantial Equivalence:	The following device characteristics were compared for substantial equivalence between the predicate devices and Cadwell devices:

- Shaft length
- Handle Length
- Lead Length
- Tip Diameter/Exposure
- Shaft Material
- Shaft Insulation
- Handle Material
- Lead Wire Material
- Lead Wire Insulation

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The comparison was performed for the following Cadwell / predicate combinations and the Cadwell devices were found to be substantially equivalent:

	Cadwell Probe Description	**Axon Part number**	**Medtronic Sofamor Danik P/N**
***Part Number/Probe*→**	***Ball Tip, 160***	***PSP1001***	***945PSP1001***
510(k) Number→		K062996	K014165
Feature ↓			
Shaft length	150-220mm	150-220mm	150-220mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	Ø2.3mm	Ø2.3mm	Ø2.3mm
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

***Part Number/Probe*→**	***Ball Tip, 90***	***PSP1000***	***945PSP1000***
510(k) Number→		K062996	K014165
Feature ↓			
Shaft length	80-150mm	80-150mm	80-150mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	Ø2.3mm	Ø2.3mm	Ø2.3mm
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

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	Cadwell Probe Description	Axon Part number	Medtronic Sofamor Danik P/N
Part Number/Probe➔	***Standard Monopolar***	***MNP1001***	***945MNP1001***
510(k) Number➔		K062996	K031003
Feature ⬇			
Shaft length	80-340mm	80-120mm	80-120mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	Ø0.8 x 0.8mm exp.	Ø0.8 x 0.8mm exp.	Ø0.8 x 0.8mm exp.
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

Part Number/Probe➔	***Bipolar***	***BNP2001***	***945BNP2001***
510(k) Number➔		K062996	K031003
Feature ⬇			
Shaft length	80-120mm	80-120mm	80-120mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	2mm exp.	2mm exp.	2mm exp.
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

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	Cadwell Probe Description	Axon Part number	Medtronic Sofamor Danik P/N
Part Number/Probe→	*Flush Tip Monopolar*	*FTP1001*	*945FTP1001*
510(k) Number→		K062996	K031003
Feature ↓			
Shaft length	80-150mm	80-150mm	80-150mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	Ø0.8mm x 0-0.3mm exp.	Ø0.8mm x 0-0.3mm exp.	Ø0.8mm x 0-0.3mm exp.
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

Part Number/Probe→	*Concentric*	*CNP2001*	*945CNP2001*
510(k) Number→		K062996	K031003
Feature ↓			
Shaft length	80-120mm	80-120mm	80-120mm
Handle Length	110mm	110mm	110mm
Lead Length	2000mm	2000mm	2000mm
Tip Diameter/Exposure	Ø1.3mm x 0-0.3mm exp.	Ø1.3mm x 0-0.3mm exp.	Ø1.3mm x 0-0.3mm exp.
Shaft Material	SST 316	SST 316	SST 316
Shaft Insulation	PTFE	PTFE	PTFE
Handle Material	Medical Grade ABS	Medical Grade ABS	Medical Grade ABS
Lead Wire Material	Tin Plated Copper	Tin Plated Copper	Tin Plated Copper
Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC	Medical Grade PVC

Device Testing:

The Cadwell Disposable Stimulator Probes were bench tested using standard measurement equipment to assure substantial equivalence in dimensions and construction to the predicate devices. This establishes safety and effectiveness equal to the predicate devices.

The sterilization process was validated following EN ISO11135:2007 to demonstrate that bioburden is reduced to no survivors and a sterility assurance level (SAL) of at least 10^{-6}.

Device Description:

Cadwell Disposable Stimulator Probes come sterilized in three electrical configurations and multiple lengths to accommodate stimulating through cannulas during minimally invasive surgeries:

Disposable Concentric Probes –
Localized stimulation due to coaxial nature of active and reference electrodes. Tip diameter approx 1mm. Particularly useful when working with a microscope. Disposable Concentric Probes may be bent by user to facilitate viewing access under a microscope.

Disposable Bipolar Probes –
Both active and return electrode are built into the probe. Both tips of the Disposable Bipolar Probe must be in contact with tissue for stimulation current to flow. The Bipolar Probe will stimulate a small amount of tissue, more than Concentric Probes, but less than Monopolar probes. Disposable Bipolar Probes may be bent to facilitate viewing access under a microscope.

Disposable Monopolar Probe –
The Monopolar Probe has a single active electrode and must be used in conjunction with a remote return electrode connected to the patient. The Monopolar probe is insulated to the tip with only a stimulating "ball" or "tip" exposed. Disposable Monopolar Probes may be bent to facilitate viewing access under a microscope.

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Indications for Use:

Cadwell Disposable Stimulator Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

The Cadwell Disposable Stimulator Probe is a single patient use device.

Conclusion:

Cadwell's Disposable Stimulator Probe is equivalent to chosen devices in design, materials and packaging and other characteristics of the predicate devices.

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

Cadwell Labs, Incorporated
c/o Mr. Chris Bolkan
Product Safety/Regulatory Affairs
909 North Kellogg Street
Kennewick, Washington 99336

FEB 2 3 2011

Re: K103128
Trade/Device Name: Cadwell Disposable Monopolar/Bipolar/Concentric/ Flush Tip/ Ball Tip Probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Nerve Stimulator
Regulatory Class: Class II
Product Code: ETN
Dated: December 16, 2010
Received: December 21, 2010

Dear Mr. Bolkan:

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

CADWELL **Indications for use**

Cadwell Disposable Stimulator Probe Indications for Use

510(k) Number (if known): K 103128

Device Name: Cadwell Disposable Stimulator Probe

Indications for Use:

Cadwell Disposable Stimulator Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

The Cadwell Disposable Stimulator Probe is a single patient use device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Hoffman

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

510(k) Number K103128