K123589

CADWELL **510k Summary**

MAR 19 2013

Submitter:	Cadwell 909 N. Kellogg Street Kennewick, Washington 99336 509-735-6481
Contact Person:	Chris Bolkan Safety / Regulatory Specialist Cadwell Laboratories, Inc.
Date Prepared:	November 7, 2012
Trade Name:	Cadwell Disposable Probe Handle
Regulation Name:	Accessory to Surgical Nerve Stimulator/Locator
Regulation Number:	21 CFR 874.1820
Regulatory Classification:	Class II
Product Code:	PDQ ETN, GXZ
Classification Panel:	Ear, Nose and Throat
Predicate Devices:	Medtronic/Xomed NIM Incrementing Probe Handle NuVasive Neurovision Probe Handle
Device Description:	The Cadwell Disposable Probe Handle is a handheld, single-patient-use, sterile, disposable probe holder intended for use in a surgical setting with a Cadwell Kilowin (K971214) instrument. The Cadwell Disposable Probe Handle allows the user to interact with the surgical monitoring instrument. Cadwell Disposable Monopolar Stimulator Probes (from K103128) specific to the Cadwell Disposable Probe Handle are inserted and removed from the tip of the handle, and make contact with an electrical connector when inserted. The user can select the probe appropriate to the task at hand, removing, repositioning, or changing probes as needed. Electrical stimulation is applied to the Cadwell Disposable Monopolar Stimulator Probe, and 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.

Indications for Use:

The Cadwell Disposable Probe Handle is a component of the Cadwell Kilowin System that 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 Probe Handle is a sterile, disposable, single patient use device.

Substantial Equivalence:

Data was provided which demonstrates that the Cadwell Disposable Probe Handle is substantially equivalent to previously cleared devices.

The use, design, materials and function of the subject device are considered to be the equivalent of the predicate devices.

Comparisons of Indications of Use and Features for Cadwell Disposable Probe Handle and Predicate Devices

Device	Intended Use
Cadwell Disposable Probe Handle	The Cadwell Disposable Probe Handle is used to perform precise 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 Probe Handle is a sterile, disposable, single patient use device.
Medtronic/Xomed NIM Incrementing Probe	This device is intended for use in surgical procedures for patient-connected intraoperative nerve monitoring, i.e. assisting the surgeon in locating and mapping motor nerves through the use of electromyographic (EMG) signals and electrical stimulus of nerves. This device is indicated for locating and identifying cranial and peripheral motor nerves during surgery, including spinal nerve roots.
NuVasive Neurovision Probe Handle	The NeuroVision JJB System is used for intraoperative monitoring and neurological status assessment by the administration of brief electrical stimulus pulses to neural tissues and the EMG monitoring of the associated muscle groups. The System is used in conjunction with other NuVasive devices to assist in gaining controlled access to, and visualization of, the spine.

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	Medtronic/Xomed Incrementing Probe Handle	NuVasive Neurovision Probe Handle	Cadwell Disposable Probe Handle
Compatible Surgical Monitoring Instrument	Medtronic NIM Eclipse (K061113)	NuVasive NVM5 (K112718)	Cadwell Kilowin (K971214)
Stimulator Probes	Detachable, Disposable, Monopolar Ball or Flush Tip	Detachable, Disposable, Monopolar	Detachable, Disposable, Monopolar Ball or Flush Tip
Electrical Insulation	Electrical insulation on surfaces not intended to provide electrical stimulation	Electrical insulation on surfaces not intended to provide electrical stimulation	Same
IEC 60601-1 Protected Pin Design	Touch Proof Handle Connector	Touch Proof Handle Connector	Same
Patient Contact Material	Stainless Steel Stimulator Probe with Insulated Shaft	Stainless Steel Stimulator Probe with Insulated Shaft	Same
Handle Material	Plastic	Plastic	Medical Grade Polycarbonate Plastic
Use and Delivery	Single use and sterile	Single use and sterile	Same
Lead Wire Insulation	Medical Grade Plastic	Medical Grade Plastic	Same
Use and Delivery	Single use and sterile	Single use and sterile	Same
Actuators	Yes	Yes	Same
Theoretical Maximum Voltage	400 V	300 V	400 V
Stimulation Current	0-100 mA	0-90 mA	0-100 mA
Stimulation Waveform	Monophasic and Biphasic	Monophasic	Monophasic and Biphasic
Maximum Pulse/S	100	5	100

Testing: Software verification and validation, sterility protocol development and validation, and electromagnetic compatibility testing were performed.

Conclusion: The Cadwell Disposable Probe Handle is substantially equivalent to predicate devices in design, materials, packaging, use, technology, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 19,2013

Cadwell Laboratories
c/o Mr. Chris Bolkan
Regulatory Affairs Engineer
909 N. Kellogg Street
Kennewick, WA 99336

Re: K123589/S001
Trade/Device Name: Cadwell Disposable Probe Handle
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical nerve locator
Regulatory Class: Class II
Product Code: PDQ, ETN, GXZ
Dated: January 24, 2013
Received: February 15, 2013

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,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K123589**

Device Name: Cadwell Disposable Probe Handle

Indications For Use:

The Cadwell Disposable Probe Handle is a component of the Cadwell Kilowin System that 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 Probe Handle is a sterile, disposable, single patient use device.

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)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123589