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510(k) Summary of Safety and Effectiveness
Blue Torch Medical Technologies CaverMap Surgical Aid
Additional Perineal Tip

Company Name

Blue Torch Medical Technologies

Official Contact

Frederick Tobia

Device Name

Proprietary Name:	Blue Torch Medical Technologies CaverMap® Surgical Aid Perineal Tip
Common Name:	Nerve Stimulator/Locator
Classification Name(s):	21 CFR § 874.1820 Stimulator, Nerve 21 CFR § 876.4730 Probe And Director, Gastro-Urology

Predicate Devices used for Substantial Equivalence

Blue Torch Medical Technologies CaverMap Surgical Aid K970971

Intended Use

The Blue Torch Medical Technologies CaverMap Surgical Aid is intended to provide stimulation to the body to locate and identify nerves and to test their excitability.

Indications for Use

The Blue Torch Medical Technologies CaverMap® Surgical Aid Perineal Tip is an accessory stimulating tip to be used for a perineal approach to nerve stimulation. It is an addition to the Blue Torch Medical Technologies CaverMap® Surgical Aid System. The system is indicated for use in the stimulation of the cavernosal and associated parasympathetic nerves during open or laproscopic prostatectomy, prostate brachytherapy placement, prostate cryotherapy, and open colorectal (surgical) procedures in males. The device aids the physician in locating these nerves. The device is designed as an adjunct to the current open or laproscopic prostatectomy, prostate brachytherapy placement, prostate cryotherapy, and open colorectal procedures in which a nerve sparing technique is used. The Surgical Aid is not designed to replace the surgeon's expertise in mapping out the neurovascular bundles. Each physician's skill determines whether these nerves are spared regardless of any aid..

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Description

The CaverMap Surgical Aid Perineal Tip has been designed specifically for use during perineal radical prostatectomy, prostate brachytherapy, and prostate cryotherapy procedures, where a nerve sparing technique is employed.

The perineal probe tip is designed as a single electrode made from surgical stainless steel. The probe tip is encapsulated in dielectrical insulating tubing, with the exception of the tip which is exposed to deliver the stimulation to the nerves. The tip also includes graduated length markings below the insulating tubing. The surface area of the stimulating (exposed) trocar tip is the same as the current electrodes of the currently marketed probe tip, giving the electrode the same charge density profile as the currently marketed probe tips.

A new reusable control handle was also designed in order to allow for a proper connection to the new probe tip. The materials used to manufacture the new handle are exactly the same as the currently marketed product.

The perineal probe tip functions exactly the same as the existing probe tip. The new tip was designed for use during nerve sparing procedures where a perineal approach to stimulating the cavernosal nerves is indicated.

Summary of Standards Achieved

FDA Quality Systems Regulation 21 CFR § 820
ISO 46001: Quality System
EN 60601-1
ISO 10993

Summary

In summary, the Blue Torch Medical Technologies CaverMap Surgical Aid Perineal Tip is substantially equivalent to legally marketed devices. Quality System & Design Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2004

Mr. Frederick Tobia
Regulatory Consultant
Blue Torch Medical Technologies, Inc.
200 Homer Avenue
Ashland Technical Center
ASHLAND MA 01721

Re: K041732
Trade/Device Name: Blue Torch Medical Technologies CaverMap®
Surgical Aid Perineal Probe Tip
Regulation Number: 21 CFR §874.1820
Regulation Name: Surgical nerve stimulator/locator
Product Code: 77 ETN
Regulation Number: 21 CFR §876.4730
Regulation Name: Manual gastroenterology-urology surgical instrument and accessories
Product Code: 78 FGM
Regulatory Class: II
Dated: August 23, 2004
Received: August 25, 2004

Dear Mr. Tobia:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041732

Device Name: Blue Torch Medical Technologies CaverMap® Surgical Aid Perineal Probe Tip

Indications for Use: The Blue Torch Medical Technologies CaverMap® Surgical Aid Perineal Tip is an accessory stimulating tip to be used for a perineal approach to nerve stimulation. It is an addition to the Blue Torch Medical Technologies CaverMap® Surgical Aid System. The system is indicated for use in the stimulation of the cavernosal and associated parasympathetic nerves during open or laproscopic prostatectomy, prostate brachytherapy placement, prostate cryotherapy, and open colorectal (surgical) procedures in males. The device aids the physician in locating these nerves. The device is designed as an adjunct to the current open or laproscopic prostatectomy, prostate brachytherapy placement, prostate cryotherapy, and open colorectal procedures in which a nerve sparing technique is used. The Surgical Aid is not designed to replace the surgeon's expertise in mapping out the neurovascular bundles. Each physician's skill determines whether these nerves are spared regardless of any aid.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041732