K031527

JUN - 5 2003

## 510(k) Summary of Safety and Effectiveness
## Blue Torch Medical Technologies® CaverMap Surgical Aid With Video Monitor

### Company Name

Blue Torch Medical Technologies® Corporation

### Official Contact

Frederick Tobia
Director, Regulatory Affairs and Quality Assurance

### Device Name

| | |
|---|---|
| Proprietary Name: | Blue Torch Medical Technologies CaverMap® Surgical Aid with Video Monitor |
| Common Name: | Nerve Stimulator/Locator |
| Classification Name(s): | 21 CFR § 874.1820 Stimulator, Nerve<br>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 Video Monitor is a modification 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 and open colorectal (surgical) procedures in males. The device aids the surgeon in locating these nerves. The device is designed as an adjunct to the current open or laproscopic prostatectomy 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 surgeon's skill determines whether these nerves are spared regardless of any aid..

### Description

The CaverMap Surgical Aid Monitor consists of a self contained IBM compatible computer system with an integrated liquid plasma video screen. The integrated video display unit will be connected to the CaverMap Surgical Aid Control unit by a standard RS-232 port.

The CaverMap Surgical Aid Monitor reads data directly from the CaverMap Surgical Aid Control Unit through a RS232 port, which will be a modification to the current control unit design. The video monitor displays the data to the video screen in text and graphical format. Communication between the CaverMap Surgical Aid and the CaverMap Surgical aid Monitor is unidirectional.

The information displayed is:

- *Tumescence Signal*
- *Baseline and Threshold Tumescence Signals*
- *Status Indication*
- *Stimulation Current.*
- *Time and Seconds Counter*
- *Error Messages*

## Summary of Standards Achieved

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

## Summary

In summary, the Blue Torch Medical Technologies CaverMap Surgical Aid Video Monitor 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

JUN - 5 2003

Blue Torch Medical Technologies, Inc.
c/o Mr. Frederick Tobia
Director, RA/ QA
CareStat
180 Wells Avenue
NEWTON MA 02459

Re: K031527
Trade/Device Name: CaverMap® Surgical Aid with Video Monitor
Regulation Number: 21 CFR §874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: II
Product Code: 77 ETN
Regulation Number: 21 CFR §876.4730
Regulation Name: Manual gastroenterology-urology surgical instrument and accessories
Regulatory Class: I
Product Code: 78 FGM
Dated: May 8, 2003
Received: May 21, 2003

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 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 this 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" (21 CFR Part 807.97). 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):** K03

**Device Name:** Blue Torch Medical Technologies CaverMap® Surgical Aid

**Indications for Use:** The Blue Torch Medical Technologies CaverMap® Surgical Aid Video Monitor is a modification 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 and open colorectal (surgical) procedures in males. The device aids the surgeon in locating these nerves. The device is designed as an adjunct to the current open or laproscopic prostatectomy 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 surgeon'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 K031527