K021804
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510(k) SUMMARY

May 30, 2002

COMPANY AND CONTACT PERSON

Julie Goode, Product Regulation Manager
Medtronic Gastroenterology/Urology
800 53rd Ave
Minneapolis, MN 55421
(763) 514-7247

TRADE NAME

Precision Plus TUNA Office System
Precision TUNA Office System
PROVu TUNA System

COMMON NAME

Electrosurgical Generator and Accessories

CLASSIFICATION NAME

Electrosurgical Cutting and Coagulation Devices and Accessories

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Precision Plus TUNA Office System, K014224
Precision TUNA Office System, K002583
PROVu TUNA System, K965061

DESCRIPTION OF DEVICE

Each system of the TUNA system product family consists of an RF generator, sterile single-use cartridge, reusable handle, reusable telescope, sterile single-use tubing set, single-use return electrode, and other accessories.

STATEMENT OF INTENDED USE

Each system of the TUNA system product family is indicated for the treat of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification 510(k) change being effected is being submitted to add a contraindication regarding the use of the TUNA System on patients implanted with neurostimulators to the labeling of the TUNA System product family.

The TUNA systems previously cleared by FDA, and currently marketed include:

- PROVu TUNA System (510(k): K965061); was deemed substantially equivalent on January 28, 1997.
- Precision TUNA Office System (510(k): K002583); was deemed substantially equivalent on February 13, 2001.
- Precision Plus TUNA Office System (510(k): K014224); was deemed substantially equivalent on January 23, 2002.

In determining substantial equivalence, the decision-making process follows the 510(k) "Substantial Equivalence" flow diagram as follows:

- The TUNA System product family with the added contraindication is being **compared to the following Marketed Device**:

  Precision Plus TUNA Office System (510(k): K014224)
  Precision TUNA Office System (510(k): K002583)
  PROVu TUNA System (510(k): K965061)

- The TUNA System product family with the added contraindication has the **same intended use** as the:

  Precision Plus TUNA Office System (510(k): K014224)
  Precision TUNA Office System (510(k): K002583)
  PROVu TUNA System (510(k): K965061)

- The TUNA System product family with the added contraindication has the **same technological characteristics** as the:

  Precision Plus TUNA Office System (510(k): K014224)
  Precision TUNA Office System (510(k): K002583)
  PROVu TUNA System (510(k): K965061).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Ms. Julie Goode
Product Regulation Manager
Medtronic, Inc.
800 53rd Avenue N.E.
MINNEAPOLIS MN 55421-1200

Re: K021804
Trade/Device Name: SEE ATTACHMENT
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Product Code: 78 KNS
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and Coagulation device and accessories
Product Code: 79 GEI
Regulatory Class: II
Dated: May 30, 2002
Received: June 3, 2002

Dear Ms. Goode:

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

K021804 ATTACHMENT

Trade/Device Name: TUNA® System Product Family, including Precision™ Plus TUNA® Office System (Model 6900 Cartridge, Model 6198 Handle, and Model 7900 Generator), Precision™ TUNA® Office System (Model 6800 Cartridge, Model 6198 Handle, and Model 7800 Generator), and PROVu™ TUNA® System (Model 6199 Cartridge, Model 6198 Handle, and Model 7600 Generator)

INDICATIONS FOR USE

510(k) Number: K021804

Device Name: **Precision Plus TUNA Office System**
Precision TUNA Office System
PROVu TUNA System

Indications for use:

The TUNA System Product Family, including Precision Plus TUNA Office System, Precision TUNA Office System, and PROVu TUNA System is indicated for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021804