K052413
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510(k) Summary

Date Summary Prepared:	August 5, 2005
Applicant:	Medtronic Gastroenterology and Urology 4000 Lexington Ave N Shoreview, MN 55126
Contact:	Julie Goode Senior Regulatory Affairs Specialist Medtronic Gastroenterology and Urology 4000 Lexington Ave N Shoreview, MN 55126 (763) 514-9670 (763) 514-9703 (fax)
Trade Name:	TUNA Therapy Model 8930 RF Generator TUNA Therapy Model 8929 Hand Piece TUNA Therapy Model 8909 Hand Piece TUNA Therapy Model 8934 Return Electrode
Common Name:	Electrosurgical generator and accessories
Classification Name:	878.4400 Electrosurgical cutting and coagulation device and accessories. 876.4300 Endoscopic electrosurgical unit and accessories
Name of Predicate Device	Precision Plus TUNA Office System (K014224) TUNA Office System (Precision) (K002583) Model 7600 RF Generator (965061) TUNA 3 (K960918)

Device Description

This premarket notification is being submitted for additional components of the Medtronic TUNA System to create two configurations of the TUNA System, branded Precision Plus and PROSTIVA. These new components include:

- Medtronic TUNA Therapy Model 8930 RF Generator
- Medtronic TUNA Therapy Model 8929 Hand Piece
- Medtronic TUNA Therapy Model 8909 Hand Piece
- Medtronic TUNA Therapy Model 8934 Return Electrode

Performance Standards

No applicable mandatory performance standards or special controls exist for this device.

Statement of Intended Use

The TUNA System is indicated for 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.

Substantial Equivalence

The components of the Medtronic TUNA System use similar technology and have the same intended uses as the predicated devices.

Component	Predicates
TUNA Therapy Model 8930 RF Generator	Medtronic Model 7900 RF Generator (K014224) Medtronic Model 7800 RF Generator (K002583) Medtronic Model 7600 RF Generator (K965061)
TUNA Therapy Model 8929 Hand Piece	Medtronic Model TUNA 3 Cartridge (K960918) Medtronic Model 6900 Cartridge (K014224)
TUNA Therapy Model 8909 Hand Piece	Medtronic Model TUNA 3 Cartridge (K960918) Medtronic Model 6900 Cartridge (K014224)
TUNA Therapy Model 8934 Return Electrode	Medtronic Model 7011 Return Electrode (K965061)

Summary of Testing

In-vitro testing was performed to support substantial equivalence to the predicate devices. The results of this testing indicate that the additional components of the Medtronic TUNA System meet all of the design and performance requirements.

Conclusion

Through the data and information presented, as well as similarities to a legally marketed device, Medtronic, Inc. considers the Medtronic TUNA System to be substantially equivalent to the previously discussed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Medtronic, Incorporated
c/o Mr. Casey Conry
Project Engineer
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K052413
Trade/Device Name: TUNA System: Models 8909 and 8929 Hand Piece,
Model 8930 RF Generator and
Model 8934 Return Electrode
Regulation Numbers: 21 CFR §876.4300 and 878.4400
Regulation Names: Endoscopic electrosurgical unit and accessories
Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Codes: KNS and GEI
Dated: October 12, 2005
Received: October 17, 2005

Dear Mr. Conry:

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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

3 Statement of Indications for Use

510(k) Number: K052413

Device Name: Medtronic TUNA Therapy Model 8909 Hand Piece
Medtronic TUNA Therapy Model 8929 Hand Piece
Medtronic TUNA Therapy Model 8930 RF Generator
Medtronic TUNA Therapy Model 8934 Return Electrode

Indications for use:

The 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.

Prescription Use ____x____ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052413