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8.0 510(K) SUMMARY

AUG 1 2 2004

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
Trade Name:	POLYGRAM NET™ Biofeedback Application
Common Name:	Biofeedback software application
Classification Name:	Gastrointestinal motility monitoring system
Name of Predicate Device	POLYGRAM Anorectal Functional Testing Application, K000386 Regain Desktop, K003127 Orion Platinum, K003367

Device Description

The POLYGRAM NET™ Biofeedback Application is used to assess and treat pelvic floor dysfunction. Data is collected in the anorectal canal, using sensors, and is displayed to the patient in a simple graphical format. The patient can modulate the activity of the anorectal muscles, thereby reeducating the pelvic floor muscles.

During a biofeedback study, a manometry catheter and/or EMG sensors are placed in the patient's anorectal canal at the sphincter. EMG sensors are then inserted anally and applied to the side of the anus. These EMG sensors, which are the same as used with the POLYGRAM Anorectal Function Testing Software (K000386), sense the patient's pelvic floor muscle activity during sequences of squeezing and relaxing maneuvers. These sensors and catheters are connected to the Medtronic Polygraf ID (K992713), which acquires the data to be displayed by the POLYGRAM NET™ Biofeedback Application.

The POLYGRAM NET™ Biofeedback Application displays a lane, that the patient navigates using their pelvic floor muscles. By squeezing and relaxing the pelvic floor muscles, the patient moves the signal level indicator up and down, trying to keep the signal level within the limits of the lane.

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Performance Standards

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

Statement of Intended Use

The POLYGRAM NET™ Biofeedback Application is intended for the assessment and treatment of pelvic floor dysfunction through biofeedback in patients 4 years of age or older.

Substantial Equivalence

This premarket notification is being submitted for the Medtronic POLYGRAM NET™ Biofeedback Application. Other Gastrointestinal motility monitoring systems, previously cleared by FDA, and currently marketed include:

- Medtronic POLYGRAM NET™ Anorectal Functional Testing Application (K000386)
- SRS Medical Systems Orion Platinum (K003367)
- SRS Medical Systems Regain Desktop (K003127)

Summary of Testing

In-vitro testing was performed to support substantial equivalence to the predicate devices. The results of this testing indicate that the Medtronic POLYGRAM NET™ Biofeedback Application meets 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 POLYGRAM NET™ Biofeedback Application 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

AUG 12 2004

Ms. Julie Goode
Senior Regulatory Affairs Specialist
Medtronic Gastroenterology and Urology
4000 Lexington Avenue North
SHOREVIEW MN 55126-2983

Re: K041244
Trade/Device Name: POLYGRAM NET™ Biofeedback Application
Regulation Number: 21 CFR §882.5050
Regulation Name: Biofeedback device
Product Code: 84 HCC
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Product Code: 78 FFX
Regulatory Class: II
Dated: May 7, 2004
Received: May 11, 2004

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 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

3.0 INDICATIONS FOR USE

510(k) Number: K041244

Device Name: POLYGRAM NET™ Biofeedback Application

Indications for use:

The POLYGRAM NET™ Biofeedback Application is intended for the assessment and treatment of pelvic floor dysfunction through biofeedback in patients 4 years of age or older.

Prescription Use ✓ **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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041244