510(k) Notification
Electrogastrography (EGG) System

510(k) SUMMARY
as required per 807.92(c)

1. Submitters Name, Address:

Medtronic A/S
Tonsbakken 16-18
DK-2740 SKOVULUNDE
Tel: + 45 44 57 90 00
Fax: + 45 44 57 90 10
Contact person for this submission: Liselotte Sander
Date submission was prepared: August 20, 2002.

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Electrogastrography (EGG) System

B. Common Name, Classification Name, Class and Regulation Number:

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Classification</th>
<th>Class</th>
<th>Regulation Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polygraf ID</td>
<td>MYE</td>
<td>II</td>
<td>21 CFR 876.1735</td>
</tr>
<tr>
<td>Polygram NET</td>
<td>MYE</td>
<td>II</td>
<td>21 CFR 876.1735</td>
</tr>
</tbody>
</table>

3. Predicate Device Identification:

The scientific technology and the functionality and intended use of the Polygram NET and the Polygraf ID are equivalent to 3CPM Company's 3CPM EGG Machine (K 984637)

4. Device Description:

The system is a stationary electrogastrography system for use in the evaluation of gastrointestinal motility disorders. The system measures the myoelectrical activity of the gastrum using sensors situated on the skin. The parameters measured are presented on a computer screen during the capture and are also stored for later display, review, analysis and reporting.

In the daily use, a trained technician, nurse and/or a physician are the main users of the system.
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The main tasks when performing an electrogastrography procedure with a stationary EGG system are:

- Prepare equipment including verification of correct levels for skin/electrode impedance levels.
- Enter patient/study demographic information
- Perform procedure and obtain relevant data
- Review, analysis and post procedure activities
- Create and print a report

The Polygram NET application software runs on the Microsoft Windows® 2000 operating system.

5. Intended Use:

The Polygaf ID with Electrogastrography (EGG) System is intended to record, store view and process gastric myoelectrical activity as an aid in the diagnosis of gastrointestinal motility disorders.

6. Table of Device Similarities and differences to predicate device

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>3CPM CO., Inc.</th>
<th>Medtronic Functional Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k) number</strong></td>
<td><strong>Predicate device</strong></td>
<td><strong>New device</strong></td>
</tr>
<tr>
<td></td>
<td>3CPM EGG Machine – K984637</td>
<td>K011468</td>
</tr>
<tr>
<td></td>
<td>Polygram NET Electrogastrography (EGG) Application:</td>
<td>Polygram NET Electrogastrography Application Software</td>
</tr>
<tr>
<td></td>
<td>• Polygraf ID</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General</th>
<th>Predicate device 3CPM</th>
<th>Modified device Polygram NET Electrogastrography (EGG) Application</th>
<th>Explanation of the differences compared to the predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC. Based</td>
<td>Yes</td>
<td>Yes</td>
<td>same</td>
</tr>
<tr>
<td>External data acquisition device</td>
<td>Yes</td>
<td>Yes</td>
<td>same</td>
</tr>
<tr>
<td>External amplifier</td>
<td>Yes</td>
<td>No</td>
<td>Better</td>
</tr>
<tr>
<td>Makes the system simpler</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of a external Strip Chart Recorder</td>
<td>Yes</td>
<td>No¹</td>
<td>Better</td>
</tr>
<tr>
<td>Makes the system simpler.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement setup</td>
<td>On HW devices</td>
<td>By use of protocol</td>
<td>Better</td>
</tr>
</tbody>
</table>

¹ The raw data is presented on the screen formatted as a strip chart. The hole recording or part's of it can be printed or included in the report.
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<table>
<thead>
<tr>
<th>Feature</th>
<th>Yes</th>
<th>SW high pass filter</th>
<th>High Pass filter³</th>
<th>Same result</th>
<th>Better</th>
<th>Better</th>
<th>Better</th>
<th>Better</th>
<th>Same result</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visualize signals in time domain.</td>
<td>Yes</td>
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<tr>
<td>Running Spectrum Analysis</td>
<td>Yes</td>
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<tr>
<td>Gain</td>
<td>100</td>
<td></td>
<td></td>
<td>0.25 Hz</td>
<td>0.25 Hz</td>
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<tr>
<td>High-Freq.</td>
<td>0.25 Hz</td>
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<td>0.25 Hz</td>
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<tr>
<td>Low Freq.</td>
<td>0.016 Hz</td>
<td></td>
<td>DC, 0.0083 Hz, 0.016 Hz, 0.030 Hz</td>
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<td>Offset</td>
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<tr>
<td>SW high pass filter</td>
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<tr>
<td>Number of channels</td>
<td>1</td>
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<td>1 to 4</td>
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<td>Motion sensor</td>
<td>Yes</td>
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<tr>
<td>Indications for use</td>
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<td>Intended populations</td>
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<td>Sterilization</td>
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<td>Biocompatibility</td>
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</table>

7. Assessment of non-clinical performance data for equivalence:
Verifications results show that the enhanced system performs as its predicate system.

² The Digital resolution is as following: Gain 1 -> 1.12 µV; Gain 10 -> 0.112 µV; Gain 100 -> 0.0112 µV
³ The Polygraf ID handles signals in the range of f ≥ 2.5 V. The DC offset is removed by use of a software high pass filter.
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8. **Assessment of clinical performance data for equivalence:**
   Clinical trials are not performed. This new system does not raise any new safety or performance issues.

9. **Biocompatibility:**
   Not applicable

10. **Sterilization:**
    Not applicable

11. **Standards and Guidances:**
    The Polygraf ID conforms to the following voluntary and mandatory standards:
    - EN 60601-1, Medical equipment
    - EN 60601-1-1, Electrical Safety
    - EN 60601-1-2, Electro magnetic Compatibility
    - CAN/CSA 22.2 No. 601.1 – M90
NOV 21 2002

Mr. Toni Kennet Jørgensen
Regulatory Affairs Specialist
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
DENMARK

Re: K014269
Trade/Device Name: Polygraf ID with POLYGRAM NET™ ElectroGastroGraphy (ECG) Application Software
Regulation Number: 21 CFR §876.1735
Regulation Name: Electrogastrography system
Regulatory Class: II
Product Code: 78 MYE
Dated: August 20, 2002
Received: August 23, 2002

Dear Mr. Jørgensen:

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
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known): K014269

Device Name: ElectroGastroGraphy (EGG) Application Software

Indications For Use:

The PolygrafID with POLYGRAM NET™ ElectroGastroGraphy Application is intended to record, store, process and view gastric myoelectrical activity as an aid in the diagnosis of gastrointestinal motility disorders.

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014269

(Optional Format 3-10-98)

Prescription Use ✔