K041934

OCT 15 2004

Premarket Notification (510(k)) Summary

1. Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Ginger Cantor Senior Regulatory Affairs Associate
Phone Number:	(651) 736-2101
FAX Number:	(651) 737-5320

Date of Summary: July 16, 2004

2. Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope, Model 3000
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 4000
3M™ Littmann® Electronic Stethoscope, Model 2000

4. Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3000 is a healthcare device that picks sounds of the heart, arteries, veins, lung and other internal organs, electronically amplifies, filters, and transfers them to the user's ears via an active speaker and passive sound tubes. The Model 3000 provides two filter frequency modes for auscultation: Bell (20-200 Hz) and Diaphragm (100-500 Hz).

The Model 3000 incorporates embedded software. The embedded software controls all of the various features found in the Model 3000 stethoscope, such as volume control and frequency mode selection. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell and diaphragm frequency response modes that are used to listen to heart, lung, and other body sounds.

The Model 3000 does not incorporate any off-the-shelf (OTS) software.

The Model 3000 operates on one (1) AAA alkaline battery.

5. Indications for Use:

The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

6. Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

The table below illustrates the similarities and differences of the new device (Model 3000) to the predicate devices (Model 4000 and Model 2000). The Model 3000 proposed under this new pre-market notification submission is composed of similar materials, and has similar performance features, intended use and indications for use as the Model 4000 cleared under K003723, and the Model 2000, cleared under K961848.

Comparison of Performance Features Littmann® Electronic Stethoscope Model 3000 versus Littmann® Electronic Stethoscope Model 4000 and Littmann® Electronic Stethoscope Model 2000

Performance Features	Model 3000 (New Device)	Model 4000 (Predicate Device) K003723	Model 2000 (Predicate Device) K961848
Frequency Response	Bell (20-200 Hz) and Diaphragm (100-500 Hz) modes.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (20-1000 Hz) modes.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (100-1000 Hz) modes.
Amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 20 dB acoustic gain, equivalent to 14 times amplification.
Maximum Sound Level	140 dB SPL Max	140 dB SPL Max	140 dB SPL Max
Power Source	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries	One (1) (AAA) alkaline battery
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	No	Yes	No
Record and Playback Sounds	No	Yes	No
Permits Data Transfer of Stored Digital Signals to and from IBM-Compatible PC and Pocket PC and Palm Pilot*	No	Yes	No
Volume Control	8 Step Volume Control	8 Step Volume Control	Continuous Variable
ON/OFF Switch Automatic Shut-off by Electronics	Yes	Yes	Yes

*** With Infrared Port and Windows /98/2000/XP, Pocket PC 2002/2003 and Palm OP Sys 4/5**
Microsoft® and Windows™ are registered trademarks of Microsoft Corporation.

7. Non-clinical (Biocompatibility) Summary:

All components of the Model 3000 stethoscope have been reviewed for biocompatibility with respect to ISO10993-Part 1 *Biological Evaluation of Medical Devices* for limited (≤ 24 hour) skin contact for both patient and/or health care professional exposure. Each component with potential skin contact with either the user or patient was reviewed for possible health concerns.

The Littmann® Electronic Stethoscope Model 3000 is composed of the same or substantially equivalent materials as those in the Littmann® Electronic Stethoscope Model 4000 cleared under K003723, and the Littmann® Electronic Stethoscope Model 2000, cleared under K961848.

3M concludes that all of the components of the Model 3000 Stethoscope would have minimal potential for any adverse health concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

3M Company
c/o Ms. Ginger Cantor
Senior Regulatory Affairs Associate
3M Healthcare
3M Center, Bldg 275-5W-06
St Paul, MN 55144-1000

Re: K041934
Trade Name: 3M Littman Electronic Stethoscope, Model 3000
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: July 16, 2004
Received: July 19, 2004

Dear Ms. Cantor:

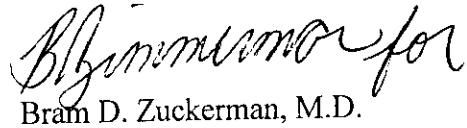
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 (301) 594-4648. 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 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
The 3M™ Littmann ® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...on Sign-Off)
...n of Cardiovascular Devices
... Number K041934