DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2005

3M Health Care
c/o Ms. Ginger Cantor, RAC (US)
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K051790
Trade Name: 3m™ Littman® Electronic Stethoscope, Model 4100
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: June 28, 2005
Received: July 1, 2005

Dear Ms. Cantor:

This letter corrects our substantially equivalent letter of July 25, 2005 regarding the model number.

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 (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 continue 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 (240) 276-0295. 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

K051790

Indications for Use Statement

510(k) Number (if known):_____

Device Name: 3M™ Littmann® Electronic Stethoscope, Model 4100

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 4100, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds of the 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_X___ OR Over-The-Counter-Use ___

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051790

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JUL 25 2005

Pre-Market 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, RAC-US Senior Regulatory Affairs Associate
Phone Number:	(651) 736-2101
FAX Number:	(651) 737-5320

Date of Summary: June 28, 2005

2. Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope, Model 4100 (Modified Model 4000)
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 4000 (K003723)

4. Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 4100 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 4100 provides three filter frequency modes for auscultation: Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (20-1000 Hz). This stethoscope provides amplification and includes features that permit it to record and store sounds on each of its six soundtracks. The recordings of the heart, lung, and other body sounds can be up to eight seconds in length on each soundtrack. The Model 4100 can play back the recordings at normal or half speed.

The Model 4100 has an infrared data transmission port that permits the recorded sounds to be transferred to another Model 4100 or to a Littmann Electronic Stethoscope Model 4000. The sounds may also be transferred to an IBM-compatible personal computer (PC) equipped with an infrared port and Windows 98/2000/XP, or to a hand-held device (i.e. a Pocket PC with Operating System 2002/2003 or Palm Pilot with Operating System 4/5).

The Model 4100 includes a liquid crystal display (LCD) on the chestpiece that displays the following information:

- Heart Rate
- Volume Level
- Track Number
- Record and Playback
- Speed of Playback (Half Speed or Normal)
- Transmit and Receive Mode
- Filter Frequency Mode
- Low-battery Indicator

The Model 4100 incorporates embedded software. The embedded software controls all of the various features found in the Model 4100 stethoscope, such as volume control, frequency mode selection, LCD display, record and playback, and the infrared data transfer. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell, diaphragm, and "extended range" frequency response modes that are used to listen to heart, lung, and other body sounds.

The Model 4100 does not incorporate any off-the-shelf (OTS) software.

The Model 4100 operates on two (2) AAA alkaline batteries.

Device modifications that are the subject of this submission include a substitution of the microphone and minor changes to software and circuits to accommodate the change. The design and materials used for the chestpiece diaphragm were also modified to accommodate this change.

The modifications included in this submission do not affect the device's intended use or indications for use. The modified device is substantially equivalent to the Model 4000 predicate device (K003723).

5. Indications for Use:

The 3M™ Littmann® Electronic Stethoscope Model 4100 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds of the 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:

Other than the one specific performance feature noted below, the Model 4100 proposed under this Special Pre-market Notification (510(k)) submission has the same performance features, intended use and indications for use as the currently marketed Model 4000 cleared under K003723. Therefore the Model 4100 is substantially equivalent to the Model 4000.

Features, Intended Use and Indications for Use	**Model 4100 (Modified Model 4000)**	**Model 4000 (Predicate Device) K003723**
Ambient Noise Reduction	Yes	No
Intended Use	Electronic Stethoscope	Electronic Stethoscope
Indications for Use	The 3M™ Littmann® Electronic Stethoscope, Model 4100, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds of the 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.	The 3M™ Littmann® Electronic Stethoscope, Model 4000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds of the 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.

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7. Non-clinical (Biocompatibility) Summary:

All components of the modified device 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 Model 4100 is composed of the same or substantially equivalent materials as those used in the Littmann® Electronic Stethoscope Model 4000 cleared under K003723.

3M concludes that none of the components of the Model 4100 would have potential for any adverse health concern.