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5.0 Premarket Notification 510(k) Summary

Sponsor Information:

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

Contact Person:	Jon Platt Regulatory Affairs Manager
Phone Number:	(651) 736-1850
FAX Number:	(651) 733-2009
eMail:	jcplatt1@mmm.com

Date of Summary:	March 7, 2012

Device Name and Classification:

Common or Usual Name:	Telemedicine Module
Proprietary Name:	3M™ Littmann® TeleSteth Online Auscultation System
Classification Name:	Transmitters and receivers, physiological signal, radiofrequency (21 CFR § 870.2910)
Performance Standards:	None

Predicate Device:

3M™ Littmann® Scope-to-Scope Software System (K101834 3M Health Care)

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Description of Device:

The 3M™ Littmann® TeleSteth Online Auscultation System, used together with the 3M™ Littmann® Model 3200 Electronic Stethoscope (K083903), allows healthcare professionals to share heart, lung and other body sounds with colleagues located across the globe using the internet or a private data network. When operational, 3M™ Littmann® TeleSteth Online Auscultation System software is physically located on a data network server and on each clients PC (see Figure 1 below). Functionally, software that is located on a clients PC establishes a wireless (Bluetooth) communications connection with a 3M™ Littmann® Model 3200 electronic stethoscope on one side and the designated network server (internet or private data network) on the other. When connected in such a way the 3M™ Littmann® Model 3200 electronic stethoscope can transmit heart, lung, and other body sounds through the clients PC to the server using secured and encrypted digital communications. Data sent to the server in such a way can then be sent on to a remotely located client PC where it can be listened to in real time (data streaming mode) by a second 3M™ Littmann® Model 3200 Electronic Stethoscope, or the sound data may be stored on the server database where it can be retrieved and listened to at a later point in time (store and forward mode).

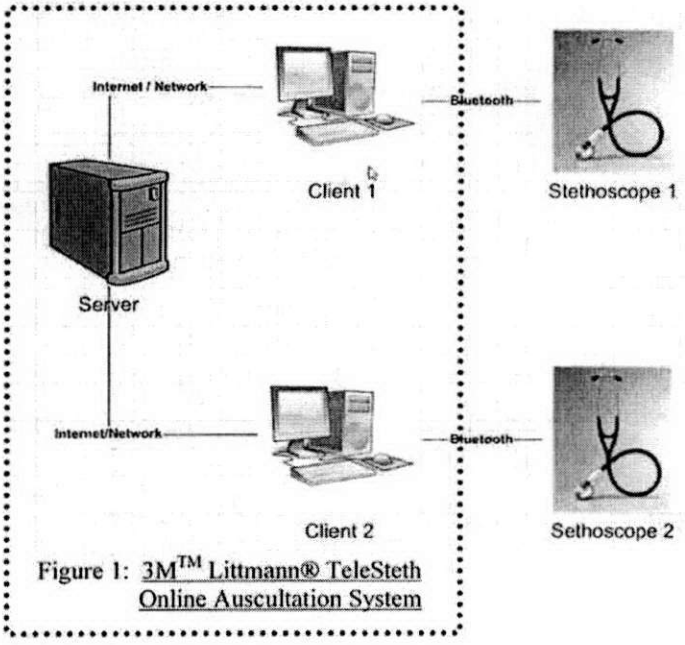

Figure 1: 3M™ Littmann® TeleSteth Online Auscultation System

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Indications for Use:

The 3M™ Littmann® TeleSteth Online Auscultation System is intended to provide and control the real time data transfer of body sounds between two 3M Littmann Electronic Stethoscopes Model 3200 over a data network. Patient body sounds may be remotely evaluated in real-time or in store-and-forward mode. The 3M™ Littmann® TeleSteth Software System can be used on any person undergoing a physical assessment.

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

Information provided in this 510(k) submission shows that the 3M™ Littmann® TeleSteth Online Auscultation System is substantially equivalent in terms of intended use, composition, physical properties and technological characteristics compared to the predicate device, the 3M™ Littmann® Scope-to-Scope Software System (K101834). There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 3 2012

3M Healthcare
c/o Mr. Jon Platt
3M Health Center, BLDG.275-05-W-06
ST. Paul, Minnesota 55144-1000

Re: K120704
Trade/Device Name: 3M™ Littmann® TeleSteth Online Auscultation System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: March 7, 2012
Received: March 8. 2012

Dear Mr. Platt:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

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4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K120704

Device Name: 3M™ Littmann® TeleSteth Online Auscultation System

Indications for Use:

The 3M™ Littmann® TeleSteth Online Auscultation System is intended to provide and control the real time data transfer of body sounds between two 3M Littmann Electronic Stethoscopes Model 3200 over a data network. Patient body sounds may be remotely evaluated in real-time or in store-and-forward mode. The 3M Littmann TeleSteth Online Auscultation System can be used on any person undergoing a physical assessment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120704