

K961848

510(k) 3M Littmann™ Electronic Stethoscope

SEP 3 1997

510(k) Summary

3M Littmann™ Electronic Stethoscope

1. **Name and address of Device Manufacturer submitting 510(k) Notification:**

3M
3M Health Care
3M Center
St. Paul, MN 55144-1000

2. **Regulatory Correspondent of Device Manufacturer:**

Linda Johnsen, Senior Regulatory Affairs Associate
612 737- 4376

3. **Date Summary was prepared:** May 10, 1996

4. **Name of Device:** 3M Littmann™ Electronic Stethoscope

5. **Predicate Device to which 3M is claiming Substantial Equivalence:**

3M Littmann Brand Electronic Stethoscope 510(k) K771653.

6. **Intended Use:**

The 3M Littmann™ Electronic Stethoscope is a diagnostic aid and used as part of a physical assessment of a patient by a Health Care Professional. It can be used for the amplification of faint heart, lung and other body sounds as well as normal auscultation and selective frequency filtering. The extended range mode amplifies sounds in a broad frequency range, including a range higher than the traditional diaphragm mode, where some lung and heart sounds may occur, as well as providing low frequency response at a slightly reduced level compared to the bell mode.

8. **Non Clinical Testing Brief Description:**

Testing to determine that the frequency response and gain are substantially equivalent to the predicate electronic stethoscope was performed with a computerized audio analysis system that sweeps a frequency oscillator from 10 to 5000 Hz. This frequency sweep is presented to a transducer on which the stethoscope is placed. The computer measures the response from the stethoscope with a small calibrated microphone placed in the eartip. The signal from the microphone is fed back to the computer where it is recorded, stored and later can be printed out. This test was done in each of the three frequency responses modes.

9. **Conclusive Statement:**

While there are some differences in the three modes, these differences are intentional and designed to beneficially provide improved frequency response in the bell mode, reduce noise pick-up in the diaphragm mode, and reduce masking of the higher frequency sounds in the extended range mode. In this way, we have determined that the present Littmann Electronic Stethoscope performs as well as, and in many cases substantially better than the predicate electronic stethoscope.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 1997

Ms. Linda Johnsen
3M Health Care
3M Center, Building 275-3E-08
St. Paul, Minnesota 55144-1000

Re: K961848
3M Littmann Electronic Stethoscope
Regulatory Class: II (two)
Product Code: 74 DQD
Dated: July 2, 1997
Received: July 3, 1997

Dear Ms. Johnsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) 3M Littmann™ Electronic Stethoscope

510(k) Number (if known): K961848

Device Name: 3M Littmann Electronic Stethoscope

Indications For Use:

Intended Use:

The 3M Littmann™ Electronic Stethoscope is a diagnostic aid and used as part of a physical assessment of a patient by a Health Care Professional. It can be used for the amplification of faint heart, lung and other body sounds as well as normal auscultation and selective frequency filtering. The extended range mode amplifies sound over a broad range of frequencies, including the range where some lung and prosthetic heart valve sounds occur.

Copy of labeling which includes instructions for use and maintenance is included in attachment 2 to the 510(k) submission.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles L. DeLoe for ABC
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K961848

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)