

JUL 19 1999

510(k) Summary

1. **Name and Address of Submitter:** Meditron AS
Leangbukta 40
N-1392 Vetre
Norway
2. **Contact Person:** Charles H. Kyper, RAC
Kyper & Associates
(301) 776-3546
3. **Date of Summary Preparation:** April 12, 1999
4. **Name of Device:** Meditron stethoscope system (electronic-amplified stethoscope)
5. **Predicate Devices:** E-scope Electronic Stethoscope Model 718-7120 (K961301)
DELWA-STAR® STETHOS™ (K963621)
SimulScope® Auscultation System (K961937)
Labtron Electromax Electronic Stethoscope Model N (K961837)
6. **Device Description and Intended Use:**

The Meditron stethoscope system is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It consists of four major components: electronic stethoscope (thestethoscope), distributor (thedistributor), connector (theconnector), and CD software (theanalyzer). Thestethoscope amplifies sounds from the body's internal organs, mainly the heart and respiratory and circulatory organs, without introducing signals or energy into the body. Thedistributor is a co-listening device that has been specially developed for teaching purposes as it permits up to six persons to listen to the patient at the same time. Thedistributor can also be used during maternity check-ups to permit the physician and expectant mother to simultaneously listen to the sounds. Theconnector (connection box and cables) links thedistributor to the sound card of a personal computer (PC). Theanalyzer is a Microsoft Windows-based CD software application supplied with theconnector and is designed to provide computer-aided recordings with the electronic stethoscope and to store these recordings along with other appropriate patient information.

7. **Brief Description of Nonclinical Testing:**

Thestethoscope is the only component of the Meditron stethoscope system that routinely comes into contact with the health practitioner and patient. Biocompatibility information for the materials in thestethoscope was provided in accordance with the CDRH Office of Device Evaluation General Program Memorandum #95-1 dated May 1, 1995, re the use of International Standard ISO-10993 (Biological Evaluation of Medical Devices Part 1: Evaluation and Testing).

Meditron AS product specifications for the environmental and electromagnetic compatibility (EMC) testing of the Meditron thestethoscope reference appropriate international standards (IEC, CISPR and EN). Environmental testing included climatic and mechanical tests and a determination of the protection provided by the enclosure against solid foreign objects and water ingress. EMC tests measured radiated emission, radiated electromagnetic field immunity, and electrostatic discharge. All product specifications were met.

8. Brief Description of Clinical Testing:

Clinical study information was not submitted for the purpose of demonstrating substantial equivalence to legally marketed electronic stethoscopes.

9. Conclusions Drawn:

The indication for use of the Meditron stethoscope system is consistent with that in the labeling for electronic stethoscopes legally marketed in the United States as well as that in the FDA classification regulation under 21 CFR 870.1875(b) for this generic type of device. Differences in technological characteristics between this device and the cited predicate devices do not raise new issues of safety or effectiveness and are addressed in the 510(k) submission. Based upon the criteria in section 513(i) of the Federal Food, Drug, and Cosmetic Act, the Meditron stethoscope system is substantially equivalent to electronic stethoscopes legally marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 1999

Meditron AS
C/O Kyper & Associates
Mr. Charles A. Kyper
11902 Simpson Road
Clarksville, MD 21029

Re: K991367
Meditron Stethoscope System
Regulatory Class: II (two)
Product Code: DQD
Dated: April 12, 1999
Received: April 20, 1999

Dear Mr. Kyper:

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 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). 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 premarket 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' (21CFR 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/dsma/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) Number (if known): K991367

Device Name: Meditron Electronic Stethoscope System

Indications For Use:

The Meditron Stethoscope System is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies sounds from the bodys internal organs, mainly the heart and respiratory and circulatory organs. It provides computer-aided recordings of these sounds and stores these recordings along with other appropriate patient information.

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

Concurrence of CDH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991367

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)