

510(k) SUMMARY
(MODELS MD-750, MD-770, MD-800)

1. COMPANY INFORMATION.

Name : Meditec Co., Ltd.

Address : #206 Ga dong, Sunnam APT. Factory, 150 Yatap-dong
Bundang-gu Sunnam-city Kyunggi-do 463-070, Korea

Phone : (011) 82-342-707-2701

Contact : Mr. D. H. Chang, President

2. DEVICE IDENTIFICATION.

- a. Trade Name : (1) Fuzzy Automatic Blood Pressure Monitor Model MD-750
(2) Fuzzy Automatic Blood Pressure Monitor Model MD-770
(3) Fuzzy Automatic Blood Pressure Monitor Model MD-800

- b. Common Name and Classification Name : Noninvasive Blood Pressure Measurement System.

3. PREDICATE DEVICE.

Sein Blood Pressure Meters, Models SE-7000, K952826

4. DEVICE DESCRIPTION.

- a. General : Three Meditec models are oscillometric systems intended for measurement of blood pressure and heart rate in a home care environment. Three models has a built-in pump for automatic inflation. Three Models include a constant air release valve to regulate deflation rate, circuitry to detect and process minute pressure oscillations, an LCD display of systolic and diastolic pressure and heart rate, and a memory function.

- b. Operation : Three models utilize a pressure measurement algorithm designed to detect, process, and store pressure readings. The pressure measurement range is 20 to 285 mmHg maintained within limits of 2 of 3 mmHg/sec to optimize measurement accuracy.

- c. Power : Three models are powered by four AA-size batteries and are equipped with a circuit that will automatically cut off power after about 3 minutes of non-use to conserve battery charge.

5. INTENDED USES.

Models MD-750, MD-770, MD-800 are intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. Because they are recommended for use in a home care environment, three models are intended to be used by patients capable of understanding written and/or oral directions.

6. COMPARISON WITH PREDICATE DEVICE.

Meditec Models(MD-750, MD-770, MD-800) has been compared with the automatically inflated Sein Model SE-7000. The intended use of the three subject devices and the predicate device is the same. The principle of operation(oscillometric measurement) is identical and there are no significant differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

7. PERFORMANCE DATA.

The measurement performance of the Meditec systems has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety and functional testing including electrical characteristics, mechanical and environmental integrity under various operating and storage conditions, high and low altitude performance, resistance to vibration and shock, life cycle testing, and intra-device variability has been performed with satisfactory results. The biocompatibility of cuff materials was evaluated favorably by TUV Product Service. Electromagnetic interference studies have been conducted by ONETECH Testing & Evaluation Laboratories and found to comply with international standards. Software verification and validation have been performed and documented. It is concluded that the subject devices comply with all relevant safety and performance standards.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meditec Co., Ltd..
c/o Ms. Carole Stamp
Responsible Third Party Official/510K Program Manager
TÜV Product Service Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112

Re: K992328
Fully Automatic Blood Pressure Monitor Models MD-750, MD-770
and MD-800
Regulatory Class: II (Two)
Product Code: DXN
Dated: July 8, 1999
Received: July 12, 1999

Dear Ms. Stamp:

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 (Premarket 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.

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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): K992328

Device Number : Noninvasive Blood Pressure Measurement system
Models MD-750, MD-770 and MD-800

Indications For Use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients, i.e., age 18 and above, in a home care environment.

(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, Respiratory,
and Neurological Devices

510(k) Number K992328

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use X

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