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K973267

Section 2 - Summary of Safety and Effectiveness for
TTM5000 - Telephonic EKG Monitor

TTM5000 Telephonic EKG Monitor is a hand held, 9 Volt battery operated ECG Event Recorder. HDS Medical Inc. has determined that TTM5000 is substantially equivalent to a predicate medical device which is currently in commerce and has been submitted to the FDA via K960499 as an Transtelephonic ECG Event Recorder and is identified as Heartrak, marketed by Universal Medical Inc.

A determination of substantial equivalance is based upon:
Both Heartrak and TTM5000 are non-invasive, 9 Volt battery operated, records 40 seconds of Electrical Heart Signals (Electrocardiogram) and transmit the audible analog signal through telephone lines. Both devices output at the transtelephonic ECG recording system are conventional ECG display.

Both device have claims or, are offered as, laboratory analysis equipment. Both are for remote convenience and easy response.

TTM5000 has benefited from design, development, testing and production procedures that conform to Good Manufacturing Procedures. This device has performance characteristics substantially equivalent to its predicate device yet includes improvements to facilitate in ease of use.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. HDS Medical Inc. continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information.

CERTIFICATION:

I hereby certify that this **Summary of Safety and Effectiveness** applies for the above indicated device.

Semih Cirit

Semih Cirit
President
HDS Medical inc.
2 Faire Winds
Laguna Niguel, CA 92677
Tel: 714-248-8587

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Mr. Semih Cirit
HDS Medical Inc.
2 Faire Winds
Laguna Niguel, CA 92677

Re: K973267
TTM5000 Telephonic EKG Monitor
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: November 25, 1997
Received: November 26, 1997

Dear Mr. Cirit:

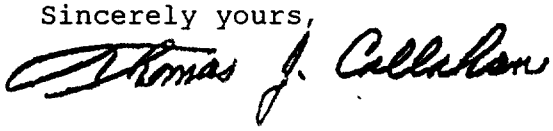
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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.

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

K973267/A1

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510(k) Number (if known): K973267

Device Name: TTM5000 TELEPHONIC EKG MONITOR

Indications For Use:

TTM5000 is a fully featured, non-invasive 9 Volt battery operated ECG (Electrocardiogram) Event Recorder. The intended use of TTM5000 is to record electrical heart signals (Electro-cardiogram) of the patient. The recorded analog data can be transmitted over the telephone lines to a transtelephonic ECG receiving system. it is used mainly by Cardiologists and Internists to detect transient arrhythmias. The device is also called arrhythmia recorder.

(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 _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

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