K021087
page 1 of 1

OCT 11 2002

510(k) Summary

1. Name/Address of Submitter: eRecords Limited
   314-801 York Mills Road
   Toronto, Ontario M3B 1X7
   Canada

2. Contact Person: Edward A. Goss
   General Manager
   416) 383-0046

3. Date Summary Prepared: March 26, 2002

4. Device Name: Hippocrat Model DR300 Electronic Stethoscope

5. Predicate Devices: Meditron Electronic Stethoscope,
   3M Littmann Electronic Stethoscope - Model 4000

6. Device Description and Intended Use:

   The Hippocrat Electronic Stethoscope is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies, records, stores, plays back, and transmits sounds associated with the heart, arteries, and veins and other internal organs. Significant components include a control unit, installation software; and power supply/charger. The user must supply a personal computer with a Microsoft Windows 98, NT 4.0, 2000, or XP operating system, CD-ROM drive, and Infrared Port. The stored sounds can be transmitted via e-mail.

7. Brief Description of Nonclinical Testing:

   The specifications for the environmental and electromagnetic compatibility (EMC) testing of the Hippocrat reference appropriate international standards. 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 indications for use are consistent with those for legally marketed electronic Stethoscopes and in the applicable FDA classification regulation. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness and are addressed in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

eRecords Limited
c/o Mr. Edward A. Goss
Vice President Business Development
801 York Mills Road, Suite 314
Toronto, Ontario M3B 1X7
Canada

Re: K021087
Trade Name: Hippocrat Model DR300 Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: August 20, 2002
Received: August 21, 2002

Dear Mr. Goss:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for

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

Enclosure

K021087

Indication for Use

510(k) Number (if known): K021087

Device Name: Hippocrat Model DR300 Electronic Stethoscope

Indication for Use:

The Hippocrat is an electronically amplified device intended for use in projecting the sounds associated with the heart and other internal organs. The Hippocrat records, stores, plays back, and electronically transmits these sounds.

Concurrence of CDRH Office of Device Evaluation

Prescription Use X OR Over-the-counter Use ____
(per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021087