



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT / 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cambridge Heart, Inc.
c/o Mr. John Greenbaum
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K981697
CH 2000 Cardiac Diagnostic System (Modified)
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: July 25, 1998
Received: July 27, 1998

Dear Mr. Greenbaum:

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" (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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first name "Thomas" being the most prominent part.

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): K981697

Device Name: Model CH 2000 Cardiac Diagnostic System

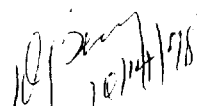
Indications For Use:

The CH 2000 is intended for the recording of electrocardiograms and vector cardiograms by a physician, or under the direction of a physician, at rest and during ECG stress testing. ECG stress testing is indicated for diagnostic and prognostic evaluation of patients with known or suspected cardiovascular disease.

The correlation of the alternans results with a specific clinical diagnosis or prognosis, when the alternans are not visually apparent on the standard ECG has not been clinically established.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number _____