AUG 5 1998

K961798

FERGUSON MEDICAL

916-342-4133
FAX: 916-343-4541

17 March 1996

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Electrocardiograph

Common/usual name: Electrocardiograph, ECG, ECG monitor, and others

Proprietary name: CT 200 Electrocardiograph

B. Substantial equivalence: Schiller AT-1 (K946205) and AT-5/6 series of devices, as well as others.

C. Device description: The device is a battery-operated, portable, 12 lead electrocardiograph which produces a 1, 3, 6, or 12 channel printout. Data can also be displayed on a personal computer monitor, using the application software package.

D. Intended use: The device is intended for use as a diagnostic device which retrieves, records, and produces a visual display of the electrical signal produced by the heart.

E. Technological characteristics: The CT 200 device is technologically similar to other standard electrocardiographs which produce a 1, 3, 6, or 12 channel printout, and is also similar to other electrocardiographs utilizing application software.

The proposed device is powered by a rechargeable battery, and is portable.

Submitted,
FERGUSON MEDICAL
Establishment Registration Number 2937794

Frank Ferguson
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 1998

Mr. Frank Ferguson
Macquarie Medical Systems
c/o Ferguson Medical
3407 Bay Avenue
Chico, CA 95973

Re: K961798
CT 2000 Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DSP
Dated: July 23, 1998
Received: July 27, 1998

Dear Mr. Ferguson:

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.

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,

Thomas J. Callahan

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): K961798

Device Name: Macquarie CT 200 Portable Electrocardiograph

Indications For Use:

The device is intended for use as a diagnostic device which receives, records, and produces a visual display of the electrical signal produced by the heart.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, [redacted]
and Neurological Devices
510(k) Number K961798

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)