K974352

SEP 8 1998

510(k) SUMMARY

Submitted by:

Malcom Castle, President
Micromedical, Inc.
255 Revere Drive
Suite 111
Northbrook, IL 60062

Date Prepared:

November 11, 1997

Proposed Device:

CARDIOVIEW™ ECG Interpretive Software

Predicate Device:

MAX 1 Exercise Testing System

Proposed Device Description:

The proposed device is computer software which receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording, which is transmitted either locally or transtelephonically from a Micromedical™ ECG monitor using a proprietary digital data transmission protocol.

Statement of Intended Use:

CARDIOVIEW™ ECG Interpretive Software receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording, which is transmitted either locally or transtelephonically from a Micromedical™ ECG monitor using a proprietary digital data transmission protocol. Using a complex mathematical analysis of a 12 Lead ECG, the software can also provide an interpretation of the ECG recording.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Nonclinical testing was performed to compare the device to the predicate device. Testing showed the proposed device to be substantially equivalent to the predicate device. Both devices use proprietary algorithms to receive, store, analyze and interpret the ECG signal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1998

Mr. Malcom Castle
Micromedical, Inc.
255 Revere Drive, Suite 111
Northbrook, IL 60062

Re: K974352
CardioView™ 3000 Software
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: June 15, 1998
Received: June 16, 1998

Dear Mr. Castle:

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

Indication for Use

510(k) Number: Not Available

Device Name: CARDIOVIEW™ Interpretive Software

Indication for Use:

CARDIOVIEW™ 3000 interpretive software is a Windows-based program intended to interpret electrocardiograms. CARDIOVIEW™ 3000 interpretive software receives, displays and stores a single or standard 12-lead simultaneous ECG recording, which is transmitted either locally or transtelephonically from a Micromedical™ ECG monitor using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal.

Prescription ✓
mark kramer

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974352