FEB 2 1999

K990266

510(k) SUMMARY

Submitted by:

Micromedical Industries Limited
11 Technology Drive
Labrador Queensland 4215
Australia

Date Prepared:

January 26, 1999

Proposed Device:

Modified 12 Lead Simultaneous Cable

Predicate Device:

12 Lead Simultaneous Cable

Proposed Device Description:

The proposed device is a 12 Lead Simultaneous Cable to connect electrodes to an electrocardiograph or to a Micromedical™ monitor or to a software system to display the ECG signal on a personal computer.

Statement of Intended Use:

The ***12 Lead Simultaneous Cable*** acquires a patient's ECG via 10 leads connected to a patient's chest, converts the ECG signal into a digital format, and transfers this information to a Micromedical monitor or software system using a proprietary digital data transfer protocol.

The proposed device is intended to be used to acquire a patient's ECG signal and transmit it to a Micromedical™ monitor or to a PC for display.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Nonclinical testing was performed to assure that the device works with the CardioView 3000 software. Testing supported the proposed labeling change.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Mr. Stephen Cresswell
MicroMedical Industries, Ltd.
11 Technology Drive
Labrodor Queensland 4215
Austrailia

Re: K990266
12-Lead Simulataneous Cable
Regulatory Class: III (three)
Product Code: LOS
Dated: January 26, 1999
Received: January 28, 1999

Dear Mr. Cresswell:

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, ²Misbranding by reference to premarket notification² (21CFR 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:

Device Name: 12 Lead Simultaneous Cable

Indication for Use:

The 12 Lead Simultaneous Cable is used to acquire a patient's ECG via 10 leads connected to a patient's chest. It converts the ECG signal into a digital format and transfers this information to a Micromedical monitor or software system using a proprietary digital data transfer protocol.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990266