K013311

## 510(k) SUMMARY

**Submitted by:**

JAN 0 3 2002

Micromedical Industries Ltd

**Date Prepared:**

October 1, 2000

**Proposed Device:**

PocketView version of Cardioview™ 3000 software

**Predicate Device:**

Cardioview™ 3000 software

**Device Description:**

The proposed device is modification to the Cardioview™ 3000 software that allows the 12 Lead Simultaneous Cable to be linked to commercially available personal digital assistants (PDA) running the Windows CE operating system.

**Statement of Intended Use:**

PocketView ECG software is a version of Cardioview™ 3000 software, a Windows-based program intended to interpret electrocardiograms. PocketView ECG software receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal. PocketView ECG Software allows the ECG information to be displayed on a commercially available personal digital assistant (PDA) running the Windows CE operating software.

**Summary of Technological Characteristics or New Device to Predicate Devices**

The technological features of PocketView ECG do not differ significantly from Cardioview™ 3000 software. The predicate device and the modified device are identical with the exception that the modified device has the connectivity feature allowing the ECG information to be displayed on a commercially available personal digital assistant (PDA) running Windows CE operating system.

**Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests**

Nonclinical testing was performed to evaluate the modification to the predicate device. Testing verified that the modified device displayed acceptable performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2002

Mr. Stephen Cresswell
MicroMedical Industries, Ltd.
11 Technology Drive
Labrador, Queensland
AUSTRALIA

Re: K013311
Trade Name: PocketView ECG Software
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 12, 2001
Received: December 4, 2001

Dear Mr. Cresswell:

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.

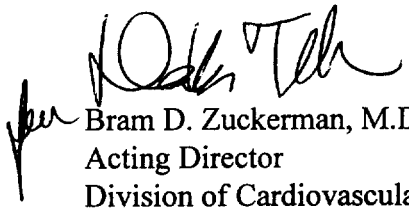
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

Enclosure

## Indication for Use

510(k) Number: K013311

Device Name: PocketView ECG Software

Indication for Use:

PocketView ECG software is a version of Cardioview™ 3000 software, a Windows-based program intended to interpret electrocardiograms, for use on a personal digital assistant (PDA). PocketView ECG software receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording which is transmitted either locally or transtelephonically using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K013311