K012540

SEP 2 6 2001

510(k) SUMMARY

Submitted by:

Micromedical Industries Ltd

Date Prepared:

August 6, 2001

Proposed Device:

BLY-501 Adaptor for Biolog™ 3000i electrocardiograph

Predicate Device:

Biolog™ 3000i electrocardiograph

Device Description:

The proposed device is an ABS plastic docking station for the Biolog™ 3000i electrocardiograph that allows the Biolog™ 3000i electrocardiograph to be connected to a LIFEPAK 500 defibrillator. The defibrillator does not have a visual display, and the connection to the Biolog™ 3000i electrocardiograph allows the patient's EKG to be visually displayed on the Biolog™ 3000i electrocardiograph to enhance the usability of the defibrillator.

Statement of Intended Use:

The Biolog™ 3000i Electrocardiograph with BLY-501 Adaptor detects an ECG using a single lead patient cable or alternatively can receive ECG data detected by the Micromedical 12 Lead Simultaneous Cable. The Biolog™ 3000i Electrocardiograph can record the ECG, display the ECG signal on a built-in LCD screen, and download the recorded ECG data to a PC running CardioView 3000 software or to the Micromedical Printer Interface. The device contains proprietary software algorithms to detect an ECG signal or receive ECG data from a patient cable, remove unwanted interference from the ECG signal, store the signal into memory, and download it to peripheral devices. The device includes a Biolog™ 3000i Electrocardiograph, a User's Manual, a BLY-501 Adaptor, and accessories. It is intended for use with the Medtronic Physio Control LIFEPAK 500 defibrillator to visually display the patient's ECG to the user of the LIFEPAK 500 defibrillator.

Summary of Technological Characteristics or New Device to Predicate Devices

The technological features of the BLY-501 do not differ significantly from the Biolog™ 3000i electrocardiograph. The predicate device and the modified device are identical with the exception that the modified device has the connectivity feature of the BLY-501 Adaptor to allow it to connect to a LIFPAK 500 defibrillator to allow a visual reading of the patient's EKG.

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

SEP 2 6 2001

Mr. Stephen Cresswell
MicroMedical Industries, Ltd.
11 Technology Drive
Labrador, Queensland 4215
Australia

Re: K012540
Trade Name: BLY-501 Adapter
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: September 17, 2001
Received: September 18, 2001

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

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) 594-4646. 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 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,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: ~~Not Available~~ K012540

Device Name: Biolog™ 3000i Electrocardiograph with BLY-501 Adaptor

Indication for Use:

The Biolog™ 3000i Electrocardiograph with BLY-501 Adaptor detects an ECG using a single lead patient cable or alternatively can receive ECG data detected by the Micromedical 12 Lead Simultaneous Cable. The Biolog™ 3000i Electrocardiograph can record the ECG, display the ECG signal on a built-in LCD screen, and download the recorded ECG data to a PC running CardioView 3000 software or to the Micromedical Printer Interface. The device contains proprietary software algorithms to detect an ECG signal or receive ECG data from a patient cable, remove unwanted interference from the ECG signal, store the signal into memory, and download it to peripheral devices. The device includes a Biolog™ 3000i Electrocardiograph, a User's Manual, a BLY-501 Adaptor, and accessories. It is intended for use with the Medtronic Physio Control LIFEPAK 500 defibrillator to visually display the patient's ECG to the user of the LIFEPAK 500 defibrillator.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012540

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