2/9/99

K990027

008

510(k) SUMMARY

Submitted by:	Del Mar Avionics 1621 Alton Parkway Irvine, CA 92606 (949) 250-3200
Contact Person:	Raphael Henkin
Date Prepared:	December 31, 1998
Proprietary Name:	Model 464 OmniCorder™
Common Name:	Holter Cassette Recorder
Classification Name:	Medical Magnetic Tape Recorder (21 CFR §870.2800)
Predicate Device:	Model 461 Pacercorder® 510(k) #K950020
Description of Device:	The Model 464 OmniCorder™ is a compact Holter ECG magnetic tape recorder utilizing standard C60 and C90 cassettes. The recorder may be used to record 2 channel ECG, 3 channel ECG, or 2 channel ECG + pseudo pacer pulses. A fourth track on the tape records a timing track for synchronized playback. Recording may be preset to a tape speed of .75 mm/sec, 1.0 mm/sec or 1.5 mm/sec. Amplitude may be preset to full or half gain. A patient event button records patient items of note on tape while maintaining the ECG signal.
Intended Use of Device:	The Model 464 OmniCorder™ is intended primarily as a Holter Recorder; recording up to three channels of ECG. The OmniCorder™ is also able to derive from ECG signals pseudo-pacer pulses representing output spikes from an implanted cardiac pacemaker. These derived pulses may be analyzed, using the Del Mar Pacer Analyzer®, to evaluate pacemaker performance and cardiac response.
Technology Considerations:	The Model 464 OmniCorder™ is similar to its predicate device with the addition of speed choice and an update to current operational amplifier technology. The motor control circuitry has been enhanced to improve high frequency noise rejection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Raphael Henkin, Ph.D.
Vice President, Technolgy and business Development
Del Mar Avionics
1621 Alton Parkway
Irvine, CA 92606-4878

Re: K990027
Trade Name: OmniCorder, Model 464
Regulatory Class: II (Two)
Product Code: DSH
Dated: December 31, 1998
Received: January 5, 1998

Dear Dr. Henkin:

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) 594-4639. 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,

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): K

Device Name: Holter OmniCorder™, Model 464

Indications for Use:

The Del Mar Avionics Model 464 DigiCorder™ is a 3-channel ECG analog cassette tape recorder. By an operator settable dip switches the recorder will perform either conventional 3-channel ECG recording or pacemaker detection recording 2 channels of ECG and 1 channel of "pseudo" pacemaker pulses each time the patient's implanted pacemaker produces a detectable pulse. A second operator selectable dip switch allows selection of recording speed at 0.5 mm/S, 1.0 mm/S or 1.5 mm/S.

The Del Mar Avionics Model 464 OmniCorder™ is intended for use as a Holter ECG cardiac-monitoring tool.

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

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990027