

510(k) Summary

Submitted by Del Mar Medical Systems
1621 Alton Parkway
Irvine, California 92606

Contact Person Nevine Erian

Date Prepared October 22, 1999

Proprietary Name Impresario™

Common Name Ambulatory ECG (Holter) Arrhythmia Analysis Software

Classification Name Programmable Diagnostic Computer

Predicate Device Del Mar Avionics Model 263 Spectrascan®

Description of Device Impresario is an arrhythmia analysis software system that allows the customer to purchase software only and install it on his/her computer. It is compatible with all Del Mar ambulatory ECG (Holter) recorders. It provides 3-channel automated arrhythmia analysis with operator intervention and edit. Reports include summary, totals, trends, histograms, and full disclosure.

Intended Use of Device The Impresario software is intended for the clinical identification of cardiac arrhythmia and normal functioning. While a trained operator can run the software, analysis of the resulting data is to be performed by a licensed physician.

Technical Considerations The fundamental technology of Impresario is the same as the predicate device. The base arrhythmia algorithm remains unchanged. The porting of the software from a DOS based system to a Windows based system allows for sale of the software alone, without the accompanying hardware dependencies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Nevine Erian
Director, Quality Assurance
and Regulatory Affairs
Delmar Medical
1621 Alton Parkway
Irvine, CA 92606

Re: K993620
Model 263 Spectrasan™ Holter System
Regulatory Class: II (two)
Product Code: DQK
Dated: October 22, 1999
Received: October 26, 1999

Dear Mr. Erian:

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.

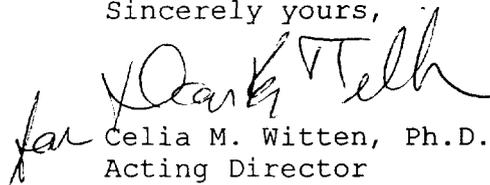
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Nevine Erian

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" (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,

for 

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

