K053369

DEC 2 2 2005

510(K) SUMMARY

[As required by 21 CFR 807.92]

1. Submitter's name, address, telephone number, and fax number

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2. Contact person

Dr J Pardey
Research and Development Manager
Huntleigh Healthcare – Cardiology Products Division.

3. Date this summary was prepared

23/11/05.

4. Name of the candidate device

Medilog Darwin Holter Analysis.

6. Classification name and number

Device Classification:	Class II.
Regulation Number :	21 CFR 870.1425 Programmable Diagnostic Computer.
Classification Panel:	74-Cardiovascular.
Product Code:	DQK.

5. Predicate device(s) to which substantial equivalence is claimed

Device Name:	Medilog Excel 3 Holter Management System.
510(k) Number:	K002544, approved by FDA on 13th September 2000.
Device Classification:	Class II.
Regulation Number :	21 CFR 870.1425 Programmable Diagnostic Computer.
Product Code:	DQK.

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6. Description of the candidate device

Medilog Darwin Holter Analysis is designed to acquire, analyse and store data recorded on Medilog series ambulatory ECG recorders. Editing facilities are offered to allow some of the information to be modified. The processed data can be printed in the form of an analysis report. The device is not a life supporting, implanted or otherwise critical device, and it is does not provide on-line warnings or alarms.

Medilog Darwin Holter Analysis is designed to operate on an industry standard PC. Customers purchase the device as a software kit for installation on their own compatible PC.

7. Intended use of the candidate device

The intended use of Medilog Darwin Holter Analysis is for the replay and analysis of data pre-recorded on Medilog series ambulatory ECG recorders.

Medilog Darwin Holter Analysis is indicated for use in the analysis, display, editing and report generation of ambulatory ECG data as part of the assessment of cardiac rhythm disturbance and myocardial ischaemia. Typically it is indicated for patients requiring analysis of 24-hour ambulatory ECG recordings as determined by a medical practioner.

It is intended that the PC on which the Medilog Darwin Holter Analysis is installed be located in a clinical environment – typically in a hospital cardiology department – and be operated by a suitably trained technician. Reports generated by the Medilog Darwin Holter Analysis are to be reviewed and interpreted by a qualified physician providing additional information in the diagnosis of the patient's condition and the determination of suitable treatment.

8. Technological characteristics

The candidate device uses a new three-channel ECG analysis algorithm, developed by the manufacturer, to analyse ECG data from Medilog series ambulatory ECG recorders.

9. Non-clinical tests performed to demonstrate substantial equivalence

The performance of the candidate device was tested on the AHA, MIT, ESC and NST databases in compliance with *ANSI/AAMI EC38:1998 Ambulatory electrocardiographs*, and *ANSI/AAMI EC57:1998 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms*. The results obtained for the candidate device were compared against available results for the predicate device. This comparison confirmed that the performance of the candidate device exceeds that of the predicate device.

In addition, parallel tests were performed in which non-paced three-channel Holter recordings from different customers were analysed using both the candidate and predicate devices. The unedited analysis results generated by each device were then

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compared against manual counts of isolated VEBs, couplets, bigeminy, trigeminy, pauses, bradycardia, tachycardia, etc. The results demonstrated that the candidate device is closer to the manual count in more cases than the predicate device.

Parallel tests were also performed on paced three-channel Holter recordings from different customers, and again the results demonstrated that the candidate device is closer to the manual count in more cases than the predicate device.

The conclusion drawn from the results of the tests described above is that the candidate device is as safe and effective, and performs as well as or better than, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Huntleigh Healthcare
c/o Mr. Olaf Teichert
TUV America, Inc.
Tuv Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K053369
Trade/Device Name: Medilog Darwin Holter Analysis
Regulation Number: 21 CFR 870.1425
Regulation Name: Computer, Diagnostic, Programmable
Regulatory Class: II (performance standards)
Product Code: DQK
Dated: December 1, 2005
Received: December 5, 2005

Dear Mr. Teichert:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

Section C
Medilog Darwin Holter Analysis 510(k)

INDICATIONS FOR USE

510(k) Number (if known): K053369

Device Name: Medilog Darwin Holter Analysis.

Indications for Use:

Medilog Darwin Holter Analysis is indicated for the replay and analysis of ECG data pre-recorded on Medilog series ambulatory recorders.

It is indicated for use in the analysis, display, editing and report generation of ambulatory ECG data as part of the assessment of cardiac rhythm disturbance and myocardial ischaemia. Typically it is intended for patients requiring analysis of 24 hour ambulatory ECG recordings as determined by a medical practitioner.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053369