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Special 510(k) Notification: Device Summary

July 14, 2006

Submitter:

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AUG 16 2006

Trade Name: DMS 300-7
Common Name: Holter ECG Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: ~~MWJ~~ DSH
Establishment Registration Number: 2028190

Legally marketed device to which S.E. is claimed:

The DMS 300-7 Holter ECG recorder is an addition to its predecessor device, Model 300 ECG Recorder, which includes a reduction in size and a battery change from 9V to AA battery power source. Its intended use, indications for use, functions, and recording output ECG data are the same as the predicate device, Model 300 ECG Recorder. The Final Test results of the predicate 300 ECG Recorder (K923664) and the modified submission device DMS 300-7, show that testing of the device with the same input signals produces the same results in the processing of the data with the same Holter playback device. This modified DMS 300-7 Holter recorder is substantially equivalent (SE) to the following legally marketed predicate devices that were cleared 510(k)s under 21 CFR 870.2800, Class II:

- Diagnostic Monitoring Software (Scole) 300 ECG Recorder (K923664).
- Datrix DR512 Holter Recorder (K982975)

Description

The modified DMS 300-7 Holter ECG recorder is intended for use as a part of a Holter analysis system and is designed to be used with the DMS Premier Holter system. The DMS 300-7 provides three (3) channels of continuous ECG recorded over a 24-hour time period. The DMS 300-7 acquires, digitizes, and stores data to be later analyzed by the Premier Holter system. The Premier Holter system processes pre-recorded patient 3-channel ECG data that has been stored in the DMS 300-7. The cardiac data provided by the DMS 300-7 recorder and the Premier

Holter system is used by trained medical personnel to assist in the diagnosis of patients with various ECG rhythm patterns.

The DMS 300-7 is a 3-channel ECG recorder that uses either a five (5) or seven (7) electrode ECG cable, as is the same with the predicate Model 300 ECG Recorder. The five (5) electrode ECG cable records a modified V1, V3, Lead II ECG recording. The seven (7) electrode ECG cable records three (3) bipolar leads, and can be used for an XYZ recording. A patient activated ECG Event button can be pressed by the patient to flag a symptomatic cardiac event ECG, as is the same with the predicate Model 300 ECG Recorder.

The DMS 300-7 uses a single AA alkaline battery as its power source, and stores acquired ECG data on a removable, non-volatile memory compact flash card. Stored ECG data is then downloaded to the hard disk drive of the Premier Holter system via a standard PCMCIA reader interface. The recorded data will remain in memory until it has been cleared by the clinician.

Comparison to the Sponsor's Predicate Devices

The DMS 300-7 is substantially equivalent (SE) to the predicate below devices.

Specifications	DMS 300-7	300 ECG Recorder	DR512
Predicate Device	No	Yes	Yes
Owner	DMS	DMS	Datrix
510(k) number		K923664	K982975
ECG Channels	3-channel ECG	3-channel ECG	3-channel ECG
Resolution	8-Bit	8-Bit	8-Bit
Recording Duration	24-hours	24-hours	24-hours
Bandwidth	0.05 to 100 Hz	0,05 to 100 Hz	0.05 to 50 Hz
Common Mode Rej	> 60 db	> 60 db	> 60 db
Power Source	AA alkaline	9V	9V or AA alkaline
Average Current Drain	5 mA	9 mA	5 mA
Event ECG Button	Yes	Yes	Yes
Operating Temp	0 to 60 C	0 to 50 C	0 to 60 C
1-MV Input =	1-CM square wave	1-CM square wave	1-CM square wave
Dimensions	4.94x2.75x0.94 in.	5.20x2.90x1.16 in.	4.94x 2.75x0.94 in.
Weight	4 oz. w/o battery	8 oz. w/o battery	4 oz. w/o battery
Processing System	Premier Holter system	Premier Holter system	Premier Holter system
ECG Data Transfer	PC's hard disk	PC's hard disk	PC's hard disk

Intended Uses and Indications for Use of the Modified Device:

The "Intended Uses" of the modified DMS 300-7 Holter recorder are exactly the same as the predicate devices (300 ECG Recorder and DR512). Its intended use is to acquire, record, and store up to 24-hours of three (3) channel ECG data for patients undergoing continuous ambulatory electrocardiography. The DMS 300-7 performs no cardiac analysis by itself and is intended to be used with the DMS Premier Holter system. The predicate devices (300 ECG Recorder and DR512) also are processed by the DMS Premier Holter system.

The "Indications for Use" of the modified DMS 300-7 Holter recorder is indicated for use in a clinical setting, by qualified medical professionals only, for recording 3-channel ECG data of patients during an ambulatory 24-hour time period. It is not a life-supporting system, and is not connected to an AC power source. Ambulatory 24-hour electrocardiography is used for the below indications:

- Evaluation of patients with symptoms suggesting arrhythmia.
- Evaluation of patients with pacemakers.
- Evaluation of patient heart rate changes.
- Evaluation of patient QRS interval changes.
- Evaluation of patient response to drug therapy treatment.

The "Indications for Use" for the modified DMS 300-7 are exactly the same as the predicate devices (300 ECG Recorder and DR512).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

AUG 16 2006

Diagnostic Monitoring Software
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Re: K062007
Trade Name: DMS 300-7
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: August 8, 2006
Received: August 8, 2006

Dear Mr. Parsons:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062007

Device Name: DMS Holter Recorder: Model DMS 300-7

Indications For Use:

The DMS 300-7 Holter ECG recorder is intended to acquire, record, and store up to 24-hours of three (3) channel ECG data for patients undergoing continuous ambulatory electrocardiography. The DMS 300-7 performs no cardiac analysis by itself and is intended to be used with the DMS Premier Holter system. In turn, the cardiac data and analysis provided by the Premier Holter system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

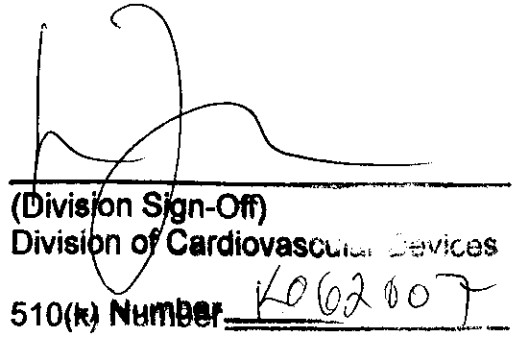
The DMS 300-7 is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of up to 24-hours. Holter ECG is appropriate for the indications below:

- .Evaluation of adult patients with symptons suggesting arrhythmia
- .Evaluation of adult patients with pacemakers
- .Evaluation of patients with suspected abnormal heart rate changes
- .Evaluation of patients with suspected abnormal QRS interval changes
- .Evaluation of patients with drug therapy treatment

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062007