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Special 510(k) Notification: Device Summary

Bundling of 300-2, 300-3, and 300-4 Holter ECG Recorders

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Submitter:

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Trade Name: DMS 300-2
DMS 300-3
DMS 300-4
Common Name: Holter ECG Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MWJ

Establishment Registration Number: 2028190
Owner/Operator Number: 9003252
Payment Identification Number: MD6027393-956733

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

This bundling of three (3) Holter ECG recorders (DMS 300-2, DMS 300-3, and DMS 300-4) are an addition to its predecessor device, Model 300-7, which has its 510(k) number issued by the FDA. The modifications are a reduction in size, a change in memory from removable flash cards to memory mounted on the circuit board, and a change in battery from AA alkaline to AAA alkaline. For these three bundled Holter ECG recorders, the intended use, indications for use, functions, and recording output ECG data are the same as the predicate device, the Model 300-7 Holter ECG recorder. The final test results of the predicate DMS 300-7 Recorder (K062007) and

the modified submission devices 300-2, 300-3, and 300-4, show that the testing of the devices with the same input signals produce the same results in the processing of the ECG data with the same Holter playback device. These modified DMS 300-2, 300-3, and 300-4 Holter recorders are substantially equivalent (SE) to the following legally marketed predicate devices that were cleared 510(k)s under 21 CFR 870.2800, Class II (two):

- Diagnostic Monitoring Software DMS 300-7 Holter ECG Recorder (K062007).
- Diagnostic Monitoring Software (Scole) 300 ECG Recorder (K923664).

The decision to submit this Special 510(k) as Bundling for these three (3) modified Holter ECG recorders was a result of a phone conversation on July 21, 2006 with Elias Mallis (301 443 8517), who recommended that this Bundling would be appropriate.

Description

DMS 300-2 Holter ECG Recorder: (Bundled device 1 of 3)

The modified DMS 300-2 Holter ECG Recorder is intended for use as a part of a Holter ECG analysis system for continuous and cardiac event monitoring, and is designed to be used with the DMS Premier Holter system. The DMS 300-2 provides three (3) leads of continuous ECG recording. With its memory built into its circuit board, the 300-2 can store up to thirty (30) days of Long-Term Ambulatory ECG, whether it be continuous ECG or patient symptomatic event ECG data. The 300-2 acquires, digitizes, and stores ECG data that can be later analyzed by the Premier Holter system. Short-term, two-minute ECG's can also be phone transmitted from the Holter recorder to a host PC for symptomatic ECG's. The Premier Holter system processes pre-recorded patient ECG data that has been stored in the DMS 300-2. The cardiac data provided by the 300-2 and the Premier Holter system is used by trained medical personnel to assist in the diagnosis of patients with various ECG rhythm patterns.

The modification differences between the predicate DMS 300-7 Holter ECG Recorder (K062007) and the 300-2 are as follows: (a) the 300-2 is a reduction in size, (b) the 300-2 has its digital memory built into the pcb; whereas, the 300-7 uses removable compact flash cards, (c) the 300-2 uses a single AAA alkaline battery, whereas the 300-7 uses a single AA alkaline battery, and (d) the 300-2 outputs a sound signal that converts to an ECG signal for testing the quality of the ECG signal and for sending symptomatic event ECG's through a phone transmission; whereas, the 300-7 uses a cable to output an ECG signal to a patient isolation source to test the quality of the ECG signal. Since digital memory has become low cost, it is a natural evolution for Holter ECG recorders to be multi-day, ambulatory, ECG recording devices. A potential problem in multi-day monitoring is that the electrode signal can deteriorate to the point that the ECG data is of no value. There is no need to waste the patient's

time in wearing a Holter recorder if the ECG signal is not of acceptable quality. The reception of the sound signal through the standard telephone at once or more per day, provides a standard ECG modality to assure that useful ECG data is being captured and being sent by the 300-2 Holter recording device.

The indications for use are the same for the predicate 300-7 device and the 300-2, the same ECG signal quality is generated by both the 300-7 and 300-2, the intended use is the same for both the 300-7 and 300-2, and the product modifications do not alter the fundamental scientific technology of the device. Data generated by the design control procedures are maintained by the manufacturer, and are available for FDA inspection. The product modifications do not significantly affect the safety and effectiveness of the 300-2.

The 300-2 is a 3-Lead ECG recorder which includes a patient activated ECG Event button that can be pressed by the patient to flag a symptomatic cardiac event ECG, as is the same with both of the listed predicate devices; namely, the DMS 300-7 (K062007) and Model 300 ECG Recorder (K923664).

DMS 300-3 Holter ECG Recorder: (Bundled device 2 of 3)

The modified DMS 300-3 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 300-3 provides three (3) channels of continuous ECG recording. With its memory built into its circuit board, the 300-3 can store up to two (2) days of continuous Holter ECG data. The 300-3 acquires, digitizes, and stores data to be later analyzed by the Premier Holter system. The Premier Holter system processes pre-recorded patient ECG data that has been stored in the DMS 300-3. The cardiac data provided by the 300-3 and the Premier Holter system is used by trained medical personnel to assist in the diagnosis of patients with various ECG rhythm patterns.

The modification differences between the predicate DMS 300-7 Holter ECG Recorder (K062007) and the 300-3 are as follows: (a) the 300-3 is a reduction in size, (b) the 300-3 has its digital memory built into the circuit board, whereas the 300-7 uses removable compact flash cards, (c) the 300-3 uses a single AAA alkaline battery, whereas the 300-7 uses a single AA alkaline battery, and (d) the 300-3 records for 48 hours, whereas the 300-7 records for 24 hours.

The 300-3 is a 3-Lead ECG recorder which includes a patient activated ECG Event button that can be pressed by the patient to flag a symptomatic cardiac event ECG, as is the same with both of the listed predicate devices; namely, the DMS 300-7 (K062007) and Model 300 ECG Recorder (K923664).

The indications for use are the same for the predicate 300-7 device and the 300-3, the same ECG signal quality is generated by both the 300-7 and 300-3, the intended use is the same for both the 300-7 and 300-3, and the product modifications do not alter

the fundamental scientific technology of the device. Data generated by the design control procedures are maintained by the manufacturer, and are available for FDA inspection. The product modifications do not significantly affect the safety and effectiveness of the 300-3.

Model 300-4 Holter ECG Recorder: (Bundled device 3 of 3)

The modified DMS 300-4 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 300-4 provides twelve (12) leads of continuous ECG recording. With its memory built into its circuit board, the 300-4 can store up to two (2) days of continuous Holter ECG data. The 300-4 acquires, digitizes, and stores data to be later analyzed by the Premier Holter system. The Premier Holter system processes pre-recorded patient ECG data that has been stored in the DMS 300-4. The cardiac data provided by the 300-4 and the Premier Holter system is used by trained medical personnel to assist in the diagnosis of patients with various ECG rhythm patterns.

The modification differences between the predicate DMS 300-7 Holter ECG Recorder (K062007) and the 300-4 are as follows: (a) the 300-4 is a reduction in size, (b) the 300-4 has its digital memory built into the circuit board, whereas the 300-7 uses removable compact flash cards, (c) the 300-4 uses a single AAA alkaline battery, whereas the 300-7 uses a single AA alkaline battery, (d) the 300-4 records 12-Leads of ECG data, whereas the 300-7 records 3-Lead of ECG data, and (e) the 300-4 records for 48 hours, whereas the 300-7 records for 24 hours.

The 300-4 is a 12-Lead ECG recorder which includes a patient activated ECG Event button that can be pressed by the patient to flag a symptomatic cardiac event ECG, as is the same with both of the listed predicate devices; namely, the DMS 300-7 (K062007) and Model 300 ECG Recorder (K923664).

The indications for use are the same for the predicate 300-7 device and the 300-4, the same ECG signal quality is generated by both the 300-7 and 300-4, the intended use is the same for both the 300-7 and 300-4, and the product modifications do not alter the fundamental scientific technology of the device. Data generated by the design control procedures are maintained by the manufacturer, and are available for FDA inspection. The product modifications do not significantly affect the safety and effectiveness of the 300-4.

Diagnostic Monitoring Software maintains its file per the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a change to an Existing Device, 510(k) Memorandum # K97-1, January 10, 1997, from the Director, Office of Device Evaluation." The process since 2000 has documented that the DMS Holter recorders have met the requirements of "Documentation" rather than "New 510(k)." Forms 2891 and 2892 have been submitted annually to the FDA. In June of 2006, DMS voluntarily asked the FDA to review our "Documentation" versus "New 510(k)" files,

and the FDA requested that we submit a New 510(k). On July 10, 2006, we spoke on the phone with the FDA's Rod Perez (800 636 2041), and he confirmed that we should submit a New Special 510(k) for the modified Holter ECG recorder. On August 16, 2006 the FDA granted to us final 510(k) marketing approval for the DMS 300-7 Holter Recorder with K062007. In a phone conversation with Elias Mallis on July 21, 2006, he recommended that we should submit the 300-2, 300-3, and 300-4 Holter recorders as a Bundled submission.

Comparison to the Sponsor's Predicate Devices:

The DMS 300-2 is substantially equivalent (SE) to the predicate below devices.

Specifications	DMS 300-2	DMS 300-7	300 ECG Recorder
Predicate Device	No	Yes	Yes
Owner	DMS	DMS	DMS
510(k) number		K062007	K923664
ECG Leads	3-Lead ECG	3-Lead ECG	3-Lead ECG
Resolution	8-Bit	8-Bit	8-Bit
Recording Duration	30-days	24-hours	24-hours
Bandwidth	0.05 to 100 Hz	0.05 to 100 Hz	0.05 to 100 Hz
Common Mode Rej	> 60 db	> 60 db	> 60 db
Power Source	AAA Alkaline	AA Alkaline	9V or AA Alkaline
Average Current Drain	3 mA	5 mA	9 mA
Event ECG Button	Yes	Yes	Yes
Operating Temp	0 to 60 C	0 to 60 C	0 to 50 C
1-MV Input =	1-CM square wave	1-CM square wave	1-CM square wave
Dimensions	2.90 x 2.16 x 0.75 in.	4.94 x 2.75 x 0.94 in.	5.20 x 2.90 x 1.16 in.
Weight	2 oz. w/o battery	4 oz. w/o battery	8 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

The DMS 300-3 is substantially equivalent (SE) to the predicate below devices.

Specifications	DMS 300-3	DMS 300-7	300 ECG Recorder
Predicate Device	No	Yes	Yes
Owner	DMS	DMS	DMS
510(k) number		K062007	K923664

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ECG Leads	3-Lead ECG	3-Lead ECG	3-Lead ECG
Resolution	8-Bit	8-Bit	8-Bit
Recording Duration	48-hours	24-hours	24-hours
Bandwidth	0.05 to 100 Hz	0.05 to 100 Hz	0.05 to 100 Hz
Common Mode Rej	> 60 db	> 60 db	> 60 db
Power Source	AAA Alkaline	AA Alkaline	9V or AA Alkaline
Average Current Drain	3 mA	5 mA	9 mA
Event ECG Button	Yes	Yes	Yes
Operating Temp	0 to 60 C	0 to 60 C	0 to 50 C
1-MV Input =	1-CM square wave	1-CM square wave	1-CM square wave
Dimensions	2.90 x 2.16 x 0.75 in.	4.94 x 2.75 x 0.94 in.	5.20 x 2.90 x 1.16 in.
Weight	2 oz. w/o battery	4 oz. w/o battery	8 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

The DMS 300-4 is substantially equivalent (SE) to the predicate below devices.

Specifications	DMS 300-4	DMS 300-7	300 ECG Recorder
Predicate Device	No	Yes	Yes
Owner	DMS	DMS	DMS
510(k) number		K062007	K923664
ECG Leads	12-Lead ECG	3-Lead ECG	3-Lead ECG
Resolution	8-Bit	8-Bit	8-Bit
Recording Duration	48-hours	24-hours	24-hours
Bandwidth	0.05 to 100 Hz	0.05 to 100 Hz	0.05 to 100 Hz
Common Mode Rej	> 60 db	> 60 db	> 60 db
Power Source	AAA Alkaline	AA Alkaline	9V or AA Alkaline
Average Current Drain	3 mA	5 mA	9 mA
Event ECG Button	Yes	Yes	Yes
Operating Temp	0 to 60 C	0 to 60 C	0 to 50 C
1-MV Input =	1-CM square wave	1-CM square wave	1-CM square wave
Dimensions	2.90 x 2.16 x 0.75 in.	4.94 x 2.75 x 0.94 in.	5.20 x 2.90 x 1.16 in.
Weight	2 oz. w/o battery	4 oz. w/o battery	8 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Diagnostic Monitoring Software
c/o Mr. William Parsons
Official Correspondent
P.O. Box 3109
Stateline, NV 89449

Re: K062959
Trade Name: DMS Holter Recorders: Models 300-2, 300-3, and 300-4
Regulation Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph without analysis
Regulatory Class: Class II
Product Code: 74 MWJ
Dated: September 19, 2006
Received: September 29, 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- 2041. 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,

B Zuckerman for

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

Enclosure

K062959

Indications for Use

510(k) Number (if known):

Device Name: DMS HOLTER RECORDERS: MODELS 300-2, 300-3 and 300-4

Indications For Use: The "Indications for Use" of the modified DMS 300-2, 300-3 and 300-4 recorders are indicated for use in a clinical setting, by qualified medical professionals only, for recording multi-lead ECG data of patients during a minimum ambulatory time period of 24-hours. It is not a life supporting system, and is not connected to an AC power source. The "Intended Uses" of the modified 300-2, 300-3, and 300-4 Holter ECG Recorders are exactly the same as the predicate devices (DMS 300-7 and 300 ECG Recorder).Ambulatory multi-day electrocardiography is used for the below indications:

- Evaluation of patients with symptoms suggesting arrhythmias.
- Evaluation of patients with pacemakers.
- Evaluation of patient heart rate changes and QRS interval changes.
- Evaluation of patient response to 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 K062959