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K133014
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Special 510(k) Notification: Device Summary

300-2W Holter ECG Recorder

Date: September 16, 2013

Submitter:

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Contact: William Parsons
Submitted Device: 300-2W
Predicate Device: 300-2
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:

The elements of this **Special 510(k) Summary** include the following:

1. Legally 510(k) marketed device to which Substantial Equivalence is claimed.
2. Description.
3. Comparison to the Sponsor's Predicate Device.
4. Intended Uses and Indications for Use of the Modified Device.
5. Technology.
6. Design Control Activities Summary.
7. Compliance with Performance Standards.
8. Labeling.

9. Hazard Risk Analysis.
10. Pictures.

Legally 510(k) marketed device to which Substantial Equivalence is claimed:

In October 2006, the FDA issued its 510(k) number K062959 for the DMS Holter Recorder, Model 300-2, which is the predicate device for this submission. The Regulation Number was 21 CFR 870 2800, and the Regulation Name was Ambulatory Electrocardiograph without analysis. The Regulatory Class was Class II, and the Product Code was 74 MWJ.

The subject of this Device Modification submission is the DMS Holter Recorder, Model 300-2W. The 300-2W is a minor modification to the predicate 300-2 Holter Recorder. The modifications are (1) increasing the size of the memory storage without affecting the characteristics of the stored ECG signal, and (2) including an additional auxiliary ECG output for the traditional real-time ECG viewing of the operational status of a Holter Recorder.

The history of the predicate 300-2 device is that this 300-2W is its first modification for a submission of a Special 510(k) submission.

Principle of Device Operation:

The principle of operation of a Holter ECG recorder is that a battery powered device is worn by a patient for the purpose of a 24-hour or longer ambulatory ECG recording on either a hospital in-patient or out-patient. After the Holter ECG recording is completed, the ECG data is transferred from the Holter ECG recorder to a PC that has a Holter ECG processing software program. From the PC, a Holter ECG report is generated for a qualified physician to review. Only a licensed physician can order the Holter ECG test.

Description:

The 300-2W is a Holter Recorder that records the ECG signal in the exact same manner as the predicate 300-2 device. The 300-2W transfers the Holter ECG from its memory in the exact same manner as the predicate 300-2. The 300-2W uses the same USB cable as is used by the predicate 300-2 to transfer the Holter file from the Holter Recorder to the Holter PC. The Holter PC program processes the 300-2W Holter ECG recording with the exact same software program as is used by the 300-2 predicate device. All of the Holter ECG screen displays and print pages are exactly the same when using either the 300-2W device or the 300-2 predicate device. The Holter report from which the physician makes a diagnosis is the exact same format when using either the 300-2W device or the 300-2 predicate device. The 300-2W uses the same firmware as the predicate 300-2 to record the Holter ECG data and to transfer the Holter recording to the Holter PC. The ECG signal in the 300-2W is the same ECG signal as the

predicate 300-2. The Intended Uses of the 300-2W and the predicate 300-2 are the same. The Indications for Use of the 300-2W and the predicate 300-2 are the same. The Design Controls and Performance Standards for the 300-2W and the predicate 300-2 are from the same source processes. The manufacturing process has ISO 13485 certification.

The 300-2W and the predicate 300-2 are multi-day Holter recorders. Both the 300-2W and the predicate 300-2 use the same alkaline or lithium batteries that are off-the-shelf AA batteries. Both the 300-2W and the predicate 300-2 use off-the-shelf commercial memory chips. The 300-2W uses a larger capacity memory chip, and both recorders operate with the memory chip in the same manner. The larger commercial memory chips are now larger capacity and cost less money than 300-2 Holter ECG recorder of 2006. All Holter ECG recorders have auxiliary real-time ECG outputs. These auxiliary outputs have no effect on the safety, performance, Intended Use, or Indications for Use with either the 300-2W or the predicate 300-2. Both the 300-2W and the predicate 300-2 have two (2) auxiliary outputs. The traditional uses of these auxiliary outputs is to view the quality of the electrode application to the patient prior to leaving the doctor's office, or to see the operational ECG of the Holter recording. The 300-2W and the predicate 300-2 have the same USB auxiliary output. The 300-2W has a WiFi auxiliary output and the predicate 300-2 has a transtelephonic auxiliary output.

Both the 300-2W and the predicate 300-2 have successfully passed TUV Rheinland CE Test Reports for Holter Recorders. Both the 300-2W and the predicate 300-2 use the same ECG electrode cables. Both Holter recorders provide the physician with the same Holter ECG results. See Sections 12 and 13 for the TUV CE Test Reports.

The enclosed TUV CE Test Report 15030071 001 shows that the 300-2W Holter Recorder passed all the test specifications for EN 60601=1-2:2007; including Enclosure Electrostatic Discharge, Radiated Emission on the Frequency Range above 30 MHz, RF electromagnetic field immunity test, and Power frequency magnetic field.

A photograph of the 300-2W is listed as an attachment in the Pictures section 15.

The physical properties of both the 300-2W and the predicate 300-2 are the same. The Holter circuit board is housed in a plastic type casing. The devices are similar in size to a mobile phone. There is an input for connecting an ECG cable, and an output for transferring the ECG that is stored on a memory chip on the circuit board. It is not physically possible to connect the ECG Cable input and the ECG data transfer output at the same time. As in all Holter ECG recorders there are auxiliary outputs to view the ECG in a real-time ECG mode. The physical properties of the 300-2W have been thoroughly tested for safety and performance as shown in the attached TUV Test Reports.

The comparison chart for the Device Modification and the Predicate Device is shown on the following page.

Comparison to the Sponsor's Predicate Device:

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

Specifications	300-2W	300-2
Predicate Device	No	Yes
Owner	DMS	DMS
510(k) number		K062959
ECG Leads	3-Lead ECG	3-Lead ECG
Resolution	8-bit	8-bit
Recording Duration	30-day	30-day
Bandwidth	0.05 to 100 Hz	0.05 to 100 Hz
Common Mode Rej	>60 db	>60 db
Power Source	AA Alkaline	AAA Alkaline
Average Current Drain	3 mA	3 mA
Event ECG Button	Yes	Yes
Operating Temperature	0 to 60 C	0 to 60 C
1 MV Input =	1-CM Square Wave	1-CM Square Wave
Dimensions	4.90 x 2.75 x .94 in	4.90 x 2.75 x .94 in
Weight	3 oz. w/o battery	3 oz. w/o battery
Processing System	Premier II Holter	Premier II Holter
ECG Data Transfer	PC's hard disk	PC's hard disk

Intended Uses and Indications for Use of the Modified Device:

The "Intended Uses" of the modified 300-2W is exactly the same as the predicate device (model 300-2). The intended use is to acquire, record, and store one or more days of multi-lead ECG data for patients undergoing continuous ambulatory electrocardiography. The 300-2 performs no cardiac analysis by itself and is intended to be used only with the DMS Premier II Holter system (K062088), as is the predicate 300-2 device.

The "**Indications for Use**" of the modified DMS 300-2W recorder is 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. Ambulatory 24-hour electrocardiography is used for the below indications:

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

The "Indications for Use" for the modified 300-2W is exactly the same as the predicate 300-2 device.

Technology:

The modified 300-2W and the predicate 300-2 are both multi-channel ambulatory electrocardiograph devices that have the same intended uses and indications for use, that function in the same manner, produce the same ECG results, and are both processed by the same DMS Premier II Holter system. The Premier II Holter was granted 510(k) marketing approval in 2006 with K062088. Both devices use the same technological characteristics to record the Holter ECG.

Design Control Activities Summary:

Both the 300-2W and the predicate 300-2 Holter recorders use the same Design Control requirements that are an integral part of the manufacturing Quality System Regulation (QSR). The QSR describes the good manufacturing practices (GMP) requirements, and have been CE certified by TUV with the ISO 13485 certification. A copy of such ISO 13485 certification is attached (Section 16) as a document. Since this is a Special 510(k) submission, we hereby declare Conformance to Design Controls, and such is also attached in Section 8 as a document. The original 510(k) number for the predicate 300-2 device is K062959.

Design controls 21 CFR 820.30 were used during the development of both the 300-2W device, and its predicate 300-2 device. Such design controls are available for FDA on-site inspections.

Compliance with Performance Standards:

Design Control procedures within the Quality Management System use standards IEC 60601-1, ISO 9001, ISO 13485, EN 60601-1-2:2007, IEC 60601-2-47, 21 CFR 820.30, and MDD 93/42/EEC. These standards are listed in the Standards Data Report for 510(k)s in Section 14.

Labeling:

A picture of the 300-2W labeling is enclosed in Section 15. The label identifies the device as the 300-2W. The Holter ECG test can only be prescribed by a licensed physician.
Labeling changes:

- Does the change affect the Indications for Use? No
- Is it a change in warnings or precautions? No
- Does the change add a contraindication? No
- Does the change delete a contraindication? No
- Is the labeling being revised for clarity to insure safer or more effective use? No

CDRH Premarket Review Submission Cover Sheet:
See Section 2

510(k) Cover Letter:
See Section 3

Indications for Use Statement:
See Section 4

Premarket Notification 510(k) Statement per 21 CFR 807.93:
See Section 6

Truthful and Accuracy Statement per 21 CFR 807.87(k):
See Section 7

Declaration of Conformity for Design Controls:
See Section 8

Hazard Risk Analysis:
See Section 9

Statement of Legal Rights to Distribute Submitted Device:
See Section 10

Screening Checklist for Premarket Notification 510(k):
See Section 11

Electromagnetic Compatibility and Electrical Safety (YUV):
See Sections 12 and 13

Standards Data Report for 510(k):
See Section 14

Pictures:
See Section 15

300-2W Operator's Manual
See Section 16

Special 510(k) Criteria:

- This 510(k) is submitted for the purpose of modifying a legally marketed predicate device, and is submitted by the same holder of the 510(k) of the predicate device.
- The "Indications for Use" of the submitted device are unchanged from the predicate device.
- The scientific technology of the submitted device is unchanged from the legally marketed predicate device.
- The submission includes only summary level information.

The submission contains an "Indications for Use" statement (Section 4).

The submission contains a 510(k) Summary (this Section 5).

The submission contains a 510(k) Summary Checklist (see section11).

The submission includes a Truthful and Accurate Statement (see section 7).

The submission references the numbers of the applicable national or international standards.

The submission relied upon published guidance documentations by the FDA.

The submitter believes that this submission is properly descriptive of the submitted device, and that the device description and labeling are consistent.

The submission's Principle of Operation is described in the 510(k) Summary section.

The description of the submitted device (300-2W) is in the Description section.

The Description section identifies the device modifications and the reasons for the changes.

The history of change from the predicate device to the modified device is described in the second page of Section 5 of this submission that was identified as "Legally 510(k) marketed device to which Substantial Equivalence is claimed."

The submitter included pictures and descriptions, and submitter believes that no engineering drawings are applicable; other than those shown in the Sections 12 & 13 TUV CE Test Reports. The submitted device is not intended to be marketed with multiple components. The 300-2W Holter recorder has its ECG data transferred to a PC with the Premier II Holter program, for which 510(k) number K062088 was provided by the FDA to Diagnostic Monitoring Software in August 2006. The predicate 300-2 device uses the same Premier II Holter program.

The submitter has included the predicate device's 510(k) number (K062959), the trade name (Holter ECG Recorder), and the model number (300-2W).

The identified predicate device is consistent throughout the submission; such as, being the Substantially Equivalent predicate device.

The submission identifies the Indications for Use and the Technology of the predicate 300-2 and the modified 300-2W as the same.

The submission describes why any differences between the submitted device and the predicate device do not constitute (a) a new intended use, (b) affect safety or effectiveness, or (c) raise different questions of safety and effectiveness.

The Risk Analysis methodology as applied to the modified submission device is described in the Hazard Risk Analysis (Section 9).

Based on the Hazard Risk Analysis, the attached TUV CE Test Reports describe the verification and validation requirements that were tested and passed, and such resulted from the various components of the ISO 13485 Quality Management System of the manufacturer.

This submission includes the Declaration of Conformity with Design Controls for (1) statement that all verification and validation activities were performed by designated individuals and the results were as expected, (2) statement that manufacturing facility complies with design controls as specified by 21 CFR 820.30, and (3) statement is signed by the responsible person.

This submission includes labeling and operator's manual, which includes a description of the device, its intended use, and directions for use.

This submission includes picture of labeling changes that result from device modification; such as, CE identification and model number.

The sections on Description and Intended Uses describe that the Intended Use of the modified device has not changed as a result of the modification. Also, as described in the Label process of the operator's manual the Intended Use has not changed as a result of the modification. Also, a separate signed statement on the Indications for Use is attached in Section 4.

Cordially,

William Parsons
Official Correspondent
Diagnostic Monitoring Software

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 19, 2014

Diagnostic Monitoring Software
c/o Mr. William Parsons
Official Correspondent
290 Kingsbury Grade # 3
Stateline, NV 89449 US

Re: K133014
Trade/Device Name: Dms 300-2W Holter ECG Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph
Regulatory Class: Class II
Product Code: MWJ
Dated: April 22, 2014
Received: April 23, 2014

Dear Mr. William 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

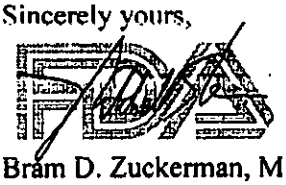
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K133014

Indications for Use

510(k) Number (if known):

Device Name: DMS Holter ECG Recorder – Model 300-2W

Indications for Use: The "Indications for Use" of the modified 300-2W recorder 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 support system, and is not connected to an AC power source. The "Indications for Use" of the modified 300-2W are exactly the same as the predicate devices (DMS 300-2 and 300-7). 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
- Evaluation of patient QRS interval changes
- Evaluation of patient response to drug therapy treatment

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

FDA Date: 2014.05.19 16:35:58 -04'00'