



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 26, 2016

Mortara Instrument, Inc.
Margaret Mucha
Director of Global Regulatory Affairs
7865 North 86th St.
Milwaukee, Wisconsin 53224

Re: K152626

Trade/Device Name: H3+ Holter Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: December 22, 2015
Received: December 23, 2015

Dear Margaret Mucha:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)

K152626

Device Name

H3+ Holter Recorder

Indications for Use (Describe)

The H3+ Holter recorder is intended to acquire, record and store continuous ECG data as directed by a clinician from adult, adolescent, pediatric, infant and neonate patient populations for a maximum recording time of 14 days in a hospital, clinic or home environment. The H3+ performs no analysis by itself and is intended to be used with a compatible ambulatory ECG (Holter) analysis system which will analyze the recorded data. The H3+ data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis.

The H3+ Holter Recorder is not a life-supporting device.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5

510(k) Summary Statement

1. Submitter

Mortara Instrument, Inc.
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2. Product Names

Device Trade Name
Common/ Usual Name
Classification

H3+ Holter Recorder
Holter Recorder
Medical Magnetic Tape Recorder
870.2800
MWJ
Cardiovascular

3. Predicate Device to which this is Substantially Equivalent

H3+ Holter Recorder

K043010

1. Device Description

The H3+ Holter Recorder is part of a Holter Analysis system. The H3+ Holter Recorder provides multiple channels of continuous multi-day ECG data recording and pacemaker spike detection markers.

The H3+ Holter Recorder is extremely small and lightweight. The H3+ includes a display that allows the clinician to confirm patient identification, preview the waveform, and check the quality of lead connections during patient hook-up. The H3+ also has a patient activated event button which allows the insertion of event marks into the recorded data if directed by the clinician.



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The H3+ uses a single battery and stores acquired data in digital form on internal, non-volatile memory. Stored data is then imported for analysis at a compatible Holter analysis system [e.g. HSCRIBE (K004017) or Vision (K945985)]. The recorded data will remain in memory until it has been cleared by the clinician.

The data provided by H3+ to the Holter Analysis system is used by trained medical personnel to assist in the diagnosis of patient conditions.

2. Intended Use

The H3+ Holter recorder is intended to acquire, record and store continuous ECG data as directed by a clinician from adult, adolescent, pediatric, infant and neonate patient populations for a maximum recording time of 14 days in a hospital, clinic or home environment. The H3+ is intended to be used with a compatible ambulatory ECG (Holter) analysis system which will analyze the recorded data. The H3+ data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis.

The H3+ Holter Recorder is not a life-supporting device.

3. Technological characteristics

The H3+ employs the same functional scientific technology as its predicate device H3+ (K043010).

4. Determination of Substantial Equivalence – Non-clinical

The H3+ was designed and tested for compliance with the applicable clauses of the following standards:

- IEC 60601-1::2012 reprint) -- Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 62304:2006, Medical device software -- Software life cycle processes
- IEC 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems. (Cardiovascular)
- IEC 60601-1-2: 2007, Medical Electrical Equipment part 1: 2. Electromagnetic Compatibility

The H3+ was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. The H3+ has undergone software validation as well as performance verification and validation to ensure it meets all design inputs and performance requirements.



The H3+ is substantially equivalent to its predicate device H3+ (K043010) as shown in the table below.

HOLTER RECORDER MODEL	Predicate Device	Current Device	Change explanation
	H3+ version 2.09	H3+ version 3.0.0	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Identical
510 (K) Number	K043010	Present Application	NA
Indications for Use	The H3+ Holter recorder is intended to acquire, record and store up to 48 hours of ECG data of patients that have been connected to the Mortara H3+ recorder and are undergoing Holter monitoring. The H3+ performs no cardiac analysis by itself and is intended to be used with the Mortara H-Scribe Holter analysis system(K0040170) or other compatible Holter Analyzer. ECG data prerecorded by the H3+ is acquired and analyzed by the H-Scribe. In turn the cardiac data and analysis provided by H-Scribe Holter system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.	The H3+ Holter recorder is intended to acquire, record and store continuous ECG data as directed by a clinician from adult, adolescent, pediatric, infant and neonate patient populations for a maximum recording time of 14 days in a hospital, clinic or home environment. The H3+ is intended to be used with a compatible ambulatory ECG (Holter) analysis system which will analyze the recorded data. The H3+ data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis. The H3+ Holter Recorder is not a life-supporting device.	Equivalent, Indications for use updated to include patient population and use environment
Type	Digital	Digital	Identical
Record duration	24 and 48 Hours	Up to 14 days	Equivalent technology but larger storage capacity
Recording medium	Internal Flash Memory	Internal Flash Memory	Identical
Data transfer method	Via USB port	Via USB port	Identical
Signal compression	Yes	Yes	Identical
Channels	2 or 3	3	equivalent, removed 2-channel functionality
sampling rate	180 sps	180 sps	Identical
Frequency Response	Meets the requirements of ANSI/AAMI EC38	Meets the requirements of IEC 60601-2-47	equivalent



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HOLTER RECORDER MODEL	Predicate Device	Current Device	Change explanation
	H3+ version 2.09	H3+ version 3.0.0	
Dynamic Range	12-bit	12-bit	Identical
Amplitude (or Digital) Resolution	6.25 uV	6.25 uV	Identical
Setup	With the graphic display and Enter key / Automatic start after 10 minutes	With the graphic display and Enter key / Automatic start after 10 minutes	Identical
ECG Channel preview	Yes	Yes	Identical
Cable	2-Channel 5-wires or 3-Channel 5-wires	3-Channel 5-wires	equivalent, removed 2-channel functionality
Test Cable	No	No	Identical
Impedance measurement	No	No	Identical
Power	1 AAA Alkaline battery up to 48 H	1 AAA Alkaline battery up to 14 days	equivalent
Pacemaker Detection	Yes	Yes	Identical
Display	Graphic LCD	Graphic LCD	Identical
Time Displayed	Yes	Yes	Identical
Carrying Case	Pouch with Belt clip & strap	Pouch with Belt clip or single-use pouch	Identical reusable pouch; added disposable pouch
Keyboard	1-button keypad	1-button keypad	Identical
Sound	No	No	Identical
Patient Event Marker	Yes	Yes	Identical
Replay and Analysis system	H-Scribe	HScribe and Vision	equivalent-added H3+ support in the Vision product
Weight	28 grams	28 grams	Identical
Dimensions	64 x 25 x 19 mm	64 x 25 x 19 mm	Identical

5. Determination of Substantial Equivalence – Clinical

The subject of this premarket notification did not require clinical data to support substantial equivalence



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6. Conclusion

The H3+ Holter Recorder is now able to store data from ambulatory recordings for a maximum of 14 days whereas the previous version of H3+ could only store data for 24 to 48 hours. This change required an updated intended use which is reflected in this submission. Other changes that were incorporated into the H3+ include removal of the 2 channel 5 wires option, compatibility with HSCRIBE and Vision Holter Analysis Systems, updated hardware components that meet the EU Restriction of Hazardous Substances Directive, addition of a Holter Prep kit and single use pouch to the list of accessories, and an added log file for service support for device use if needed.

Mortara has determined these changes did not impact the safety and efficacy of the H3+ Holter recorder. The H3+ Holter Recorder performance is substantially equivalent to the predicate device.