DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 3, 2016

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

Re: K161465
Trade/Device Name: CardioConfirm
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: August 1, 2016
Received: August 2, 2016

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.

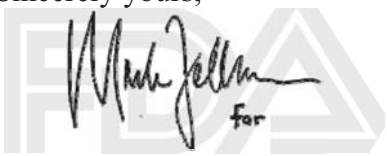
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161465

Device Name
CardioConfirm

Indications for Use *(Describe)*

CardioConfirm is intended to be used by qualified clinicians to finalize cardiology reports for adult and pediatric patients. To aid the clinician's interpretation of resting ECGs, CardioConfirm supports the display and onscreen measurement of ECG waveforms. CardioConfirm also supports the algorithmic comparison of serial adult ECGs and allows the user to edit the automatic comparison statements.

CardioConfirm is intended to be controlled by a host application that manages user authentication, user permissions, and secure persistent storage of the tests.

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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Milwaukee, WI 53224

Telephone 414-354-1600
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Primary Contact

Margaret Mucha
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2. Product Names

Device Trade Name	CardioConfirm
Common/ Usual Name	Electrocardiograph
Classification	870.2340 DPS Electrocardiograph 870.1425 DQK Computer, diagnostic, programmable Cardiovascular

Note: There are no previous submissions for this device

3. Predicate Devices to which this is Substantially Equivalent

E-Scribe (primary)	K930558
Pyramis ECG Management System	K032038

These predicate devices have not been subject to a design-related recall

4. Device Description

CardioConfirm is a software component that is embedded into a host application (e.g. EMR) as a Dynamic Link Library (DLL) or launched as an executable application. CardioConfirm allows the user to display, edit and finalize diagnostic cardiology ECG, Stress and Holter reports. A Clinician can open a diagnostic cardiology test from a workstation application and pass it to CardioConfirm as a DICOM object for viewing or editing. CardioConfirm is able to open and edit diagnostic cardiology ECG, Stress and Holter reports from Mortara Instrument, Inc. devices and offers an optional version which can edit diagnostic cardiology ECG, Stress and Holter reports from multiple diagnostic cardiology equipment vendors.

CardioConfirm allows the clinician the ability to view, measure, and compare previously acquired resting ECGs as well as perform visual and textual serial comparison of acquired ECGs. With visual serial comparison, the clinician can view current and previous ECG's simultaneously superimposed on the screen. Textual serial comparison allows the clinician to enter or edit text that describes the significant differences between the ECG's. For adult ECG's the initial text can be generated by the VERITAS SERIAL COMPARISON algorithm. The algorithm generates comparative statements automatically on the basis of the VERITAS INTERPRETATION statements originally made by the Mortara acquiring devices, measurements and the ECG waveforms. The clinician can edit the patient demographics, previous measurements and interpretations and the serial comparison statements, and then sign final ECG reports.

The clinician can also view and edit stress and Holter reports that includes editing patient demographics, summary statistics and physician conclusions. The clinician can electronically sign both stress and Holter final reports in CardioConfirm and print final reports or generate PDF copies to store in the host application. If a physician wants to amend a previously finalized report with additional information, CardioConfirm has an option to perform amendments to final reports and store the updated test in the host application.

CardioConfirm is available in two versions. The standard version is intended to be used with tests generated by Mortara equipment. The professional version is intended to be used with tests generated by any

equipment that produces DICOM 12-lead ECG Waveform and Encapsulated PDF objects.

5. Intended Use

CardioConfirm is intended to be used by qualified clinicians to finalize cardiology reports for adult and pediatric patients. To aid the clinician's interpretation of resting ECGs, CardioConfirm supports the display and onscreen measurement of ECG waveforms. CardioConfirm also supports the algorithmic comparison of serial adult ECGs and allows the user to edit the automatic comparison statements.

CardioConfirm is intended to be controlled by a host application that manages user authentication, user permissions, and secure persistent storage of the tests.

6. Technological characteristics

CardioConfirm employs the same functional scientific technology as its predicate device E-Scribe (K930558) and Pyramis ECG Management System (K032038). At a high level, all three devices employ a Windows based tool to transfer electrocardiographic data from resting ECGs, stress, and Holter exams to further process and analyze the data, prepare final reports, and archive the data and reports.

CardioConfirm was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. CardioConfirm is substantially equivalent to E-Scribe (Predicate K930558) and Pyramis ECG Management System (Predicate K032038) with the following technological differences:

- CardioConfirm is imbedded as a DLL in a host application such as an EMR or EHR
- CardioConfirm can be made available as a Windows executable file that can be controlled by a host application
- CardioConfirm can print reports and waveforms
- CardioConfirm can accept demographic updates outside of CardioConfirm
- For Resting ECG Reports:
  - CardioConfirm reads DICOM 12-Lead ECG waveform objects
  - CardioConfirm allows the user to edit previously-signed interpretations

  - CardioConfirm provides an onscreen magnifying loupe for Resting ECG waveforms
  - CardioConfirm allows the user to edit the statement prediction in reports
- For Stress and Holter Reports:
  - CardioConfirm will read DICOM Encapsulated PDF objects
  - CardioConfirm will write DICOM Encapsulated PDF objects
  - CardioConfirm will allow the user to use conclusion templates

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Data Management System	CardioConfirm	E-scribe (Primary)	Pyramis ECG Management System	Change explanation
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
Intended Use	CardioConfirm is intended to be used by qualified clinicians to finalize cardiology reports for adult and pediatric patients. To aid the clinician's interpretation of resting ECGs, CardioConfirm supports the display and onscreen measurement of ECG waveforms. CardioConfirm also supports the algorithmic comparison of serial adult ECGs and allows the user to edit the automatic comparison statements. CardioConfirm is intended to be controlled by a host application that manages user authentication, user permissions, and secure persistent storage of the	This system is designed to be used as a storage system for ECG data in hospitals and large medical clinics. The E-Scribe allows the user to store, edit and retrieve patient ECG information	The Pyramis ECG Management System is an ECG data management and information system. Its primary function is to store records of biologic origin such as ECG, Stress and Holter records received from those respective recording devices in a database and subsequently allow the user to select, view, edit, print/fax/email and export (distribute) those records	Equivalent

Traditional 510(k) Notification
K161465

Data Management System	CardioConfirm	E-scribe (Primary)	Pyramis ECG Management System	Change explanation
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
	tests.			
Operating System	Windows 7, Windows 8.1, etc.	Windows 2008 R2, Windows 7	Windows 2008, Windows 7	Equivalent
Form: DLL for embedding in a host application	Yes	Not applicable	Not applicable	New feature
Form: executable controlled by a host application	Yes	Not applicable	Not applicable	New feature
IO: option to limit to Mortara device data only	Yes	Yes	Yes	Equivalent
IO: offline PDF generation of reports	Yes	Yes	Yes	Equivalent
IO: report printing	Yes	Yes	Yes	Equivalent

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K161465

Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
User Permissions: view only	Yes	Yes	Yes	Equivalent
User Permissions: view and save	Yes	Yes	Yes	Equivalent
User Permissions: view and electronically sign	Yes	Yes	Yes	Equivalent
User Permissions: edit demographics	Yes	Yes	Yes	Equivalent
User Permissions: edit measurements	Yes	Yes	Yes	Equivalent

Traditional 510(k) Notification
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Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
View: patient identity always visible	Yes	Yes	Yes	Equivalent
View: pan and zoom	Yes	Yes	Yes	Equivalent
Edit: patient demographics	Yes	Yes	Yes	Equivalent
Edit: accepts demographic updates outside of CardioConfirm	Yes	Not applicable	Not applicable	New feature
Sign: electronically sign	Yes	Yes	Yes	Equivalent
Resting ECG				
IO: option to support non-	Yes for professional	No	Yes	Equivalent to

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Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
Mortara device data	version			Pyramis
IO: reads DICOM 12-Lead ECG Waveform objects	Yes	Not applicable	Not applicable	Equivalent to Pyramis
IO: writes DICOM 12-lead ECG Waveform objects	Yes	Yes	No	Equivalent to E-Scribe
User Permissions: edit interpretation including serial comparison and conclusion	Yes	Yes	Yes	Equivalent
View: waveform zoom	Optimizes for display of full 10s waveforms over a	Fit page, Fit width, 75%, 100%, 150%, 200%,	Fit width, Fit height, 25%, 50%, 75%, 100%, 125%,	Equivalent

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Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
	wide range of screen resolutions	300%, 400%	150%, 200%, 400%, 600%, 800%	
View: local magnification	Onscreen magnifying loupe	No	No	New feature, allows closer inspection of beat details in context of full ECG
View: channel layout	3x4, 3x4+1, 3x4+3, 6x2, 12x1, 3x5, 3x5+1, 3x5+3	3x4, 3x4+1, 3x4+3, 6x2, 12x1	15x1, 12x1, 6x2, 3x4, 3x4+1, 6x2	Equivalent
View: median beat layout	3x4, overlay	3x4, overlay	3x4	Equivalent
View: frequency filter	40 Hz, 150 Hz, None	40 Hz, 150 Hz, None	None	Equivalent to E-Scribe
View: waveform gain	5, 10, 20 mm/mV	5, 10, 20 mm/mV	None	Equivalent to E-Scribe
View: waveform	1mm, 5mm, None	1mm, 5mm, None	1mm, 5mm	Equivalent to E-

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Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
grid				Scribe
View: compare ECGs in side-by-side display	Yes	Yes	Yes	Equivalent
Edit: global measurements	Yes	Yes	Yes	Equivalent
Edit: statement acronyms	Yes	Yes	Yes	Equivalent
Edit: option to protect previously-signed interpretation	Yes	No	No	New feature, allows host applications to amend previously-signed ECGs.
Edit: statement prediction	Yes	No	No	New feature, predicts statements after entering a few

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Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
				characters
Measure: onscreen calipers	Time, Voltage, Periodicity	Time, Voltage	Time, Voltage	Equivalent
Analyze: Veritas comparison algorithm generates comparison statements for Mortara ECGs	Yes	Yes	No	Equivalent to E-Scribe
Stress and Holter				
IO: reads DICOM Encapsulated PDF objects	Yes	Not applicable	Not applicable	New feature, predicates do not accept DICOM data

Traditional 510(k) Notification
K161465

Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
IO: writes DICOM Encapsulated PDF objects	Yes	Not applicable	No	New feature, predicates do not export stress and Holter DICOM reports
User Permissions: edit conclusions	Yes	Not applicable	Yes	Equivalent to Pyramis
User Permissions: edit summary statistics	Yes	Not applicable	Yes	Equivalent to Pyramis
Edit: summary statistics	Yes	Not applicable	Yes	Equivalent to Pyramis
Edit: free-text conclusions	Yes	Not applicable	Yes	Equivalent to Pyramis
Edit: use conclusion	Yes	Not applicable	No	New feature, beyond free-text

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K161465

Data Management System	**CardioConfirm**	**E-scribe (Primary)**	**Pyramis ECG Management System**	**Change explanation**
BRAND	Mortara	Mortara	Quinton	
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Quinton Inc.	
510 (K) Number	Present Application	K930558	K032038	
templates				conclusions

7. Determination of Substantial Equivalence – Non-clinical

Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices"* and *"Off-the-Shelf Software Use in Medical Devices."* Software code reviews and unit testing were conducted as part of our overall design control process for software development and subsequent verification and validation.

Determination of Substantial Equivalence – Clinical

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

8. Conclusion

The non-clinical data that supports the safety of this device as well as the software verification and validation that have been completed at the time of this submission demonstrate that CardioConfirm performs as intended. As a result of completed verification and validation activities to date, Mortara has determined the CardioConfirm is substantially equivalent to the predicate device.