November 16, 2020

Cordiana Medical Informatics AG
Johan Sandberg
CEO
Platz 4
Root, LU 6039
Switzerland

Re: K201060
Trade/Device Name: Cordiana Dx16
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 8, 2020
Received: October 16, 2020

Dear Johan Sandberg:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Lt. Stephen Browning, USPS
Assistant Director
DHT2A: Division of Cardiac Electrophysiology,
Diagnostics, & Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201060

Device Name

Cordiana Dx16

Indications for Use *(Describe)*

Cordiana Dx16 is a web-based software system used for reference and diagnostic viewing, manual editing and printing of cardiopulmonary records, consisting of measurements, text and digitized waveforms, with associated reports and documents. Users do not need to download or install any additional software or plug-ins to use the zero-footprint browser client.

Cordiana Dx16 provides authenticated users the ability to search for, list, display, edit and confirm cardiopulmonary studies through the use of reviewing, onscreen measuring and editing tools. Cordiana Dx16 is intended for use by healthcare professionals, including (but not limited to) physicians, nurses and medical technicians, trained on the use of the software.

Cordiana Dx16 is intended to be used in hospitals or facilities providing patient care, where cardiopulmonary studies are stored in a remote storage system, such as a Picture Archive and Communication System (PACS), with which records, reports and documents can be queried, retrieved and stored using DICOM or similar interface standards.

Cordiana Dx16 does not provide storage of records or associated reports and documents, does not modify the original record and waveform information, and is not intended for real-time monitoring.

Indications for use of Cordiana Dx16 are quantification and reporting of cardiopulmonary function of patients (adults and children of any age from birth upwards) with suspected disease to support the physicians in the diagnosis.

Cordiana Dx16 does not provide automated determination of fiducial points, interpretative statements, or patient diagnosis.

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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510(k) Summary
for
Cordiana Dx16

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Sponsor

Sponsor: Cordiana Medical Informatics AG
Platz 4
CH-6039 Root D4
Switzerland

Contact Person: Johan Sandberg, CEO
Phone: +41 41 534 56 38
E-Mail: johan.sandberg@cordiana.com

Date Prepared: October 08, 2020

Device Name and Classification

Proprietary Name: Cordiana Dx16

Common/Usual Name: ECG Analysis Computer

Classification Name: Computer, Diagnostic, Programmable
(21 CFR 870.1425, Product Code DQK)

Predicate Device

Predicate Device: MUSE Cardiology Information System K152993

Intended Use

Cordiana Dx16 is a web-based software system used for reference and diagnostic viewing, manual editing and printing of cardiopulmonary records, consisting of measurements, text and digitized waveforms, with associated reports and documents. Users do not need to download or install any additional software or plug-ins to use the zero-footprint browser client.

Cordiana Dx16 provides authenticated users the ability to search for, list, display, edit and confirm cardiopulmonary studies through the use of reviewing, onscreen measuring and editing tools. Cordiana Dx16 is intended for use by healthcare professionals, including (but not limited to) physicians, nurses and medical technicians, trained on the use of the software.

Cordiana Dx16 is intended to be used in hospitals or facilities providing patient care, where cardiopulmonary studies are stored in a remote storage system, such as a Picture Archive and Communication System (PACS), with which records, reports and documents can be queried, retrieved and stored using DICOM or similar interface standards.

Cordiana Dx16 does not provide storage of records or associated reports and documents, does not modify the original record and waveform information, and is not intended for real-time monitoring.

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Indications for use of Cordiana Dx16 are quantification and reporting of cardiopulmonary function of patients (adults and children of any age from birth upwards) with suspected disease to support the physicians in the diagnosis.

Cordiana Dx16 does not provide automated determination of fiducial points, interpretative statements, or patient diagnosis.

Device Description and Function

Cordiana Dx16 is a web-based software system used for reference and diagnostic viewing, manual editing and printing of cardiopulmonary studies from various cardio-pulmonary device manufacturers.

The studies are stored in open standardized formats in a remote storage system, such as a Picture Archive and Communication System (PACS) or a Vendor Neutral Archive (VNA). Cordiana Dx16 does not provide own storage of records or associated reports and documents and does not modify records or the original waveform information stored on the remote storage system.

Authenticated users can use Cordiana Dx16 to search for, list, display, edit and confirm cardiopulmonary studies through the use of reviewing, onscreen measuring and editing tools.

The system consists of two logical parts which are installed, configured and maintained as one:

- A web server, which is installed centrally in a hospital's IT infrastructure. The Gateway serves as a stateless server to the browser clients. It also serves as a client to the remote storage system, such as the PACS/VNA, with which records, reports and documents are queried, retrieved and stored using the DICOM standard.
- Zero-footprint browser clients, which are loaded and updated on demand as single-page applications into an HTML5 enabled web-browser. Users do not need to download or install any additional software or plug-ins to use the clients.

Cordiana Dx16, when used as intended with a remote storage system, acts as a traditional cardiopulmonary data management system, such as an ECG Management System.

The clients can optionally be integrated ("embedded") as-is with an external application which provides authentication and workflow support. When authentication is done in the external application, the externally authenticated user's credentials are passed to Cordiana Dx16 using Single Sign-On Authentication. When the external application provides workflow support, the search screens are bypassed, and the user is brought directly to a requested study.

Cordiana Dx16 does not store studies or patient related information in the browser clients, does not directly communicate with cardiographs or other acquisition devices, and does not use any automatic electronic data processing and pattern recognition methods to quantify measurements (e.g. intervals and amplitudes) or provide diagnostic statements.

Cordiana Dx16 functions as a non-real-time system and is not intended for real-time monitoring.

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Predicate Device Comparison

Characteristic	New Device	Predicate Device	Similar / Different
510(k) Number	K201060	K152993	N/A
Device Trade Name	Cordiana Dx16	MUSE Cardiology Information System	N/A
Manufacturer	Cordiana Medical Informatics AG	GE Medical Systems Information Technologies, Inc.	N/A
Intended Use			
Patient Population	Adults and children of any age from birth upwards	Adult and pediatric patients	Same
Accessed and managed information	Measurements, text and digitized waveforms	Measurements, text, and digitized waveforms	Same
Functionality	Search for, list, display, edit and confirm cardiopulmonary studies through the use of reviewing, onscreen measuring and editing tools	Review and edit electrocardiographic procedures on screen, through the use of reviewing, measuring, and editing tools	Similar
User Population	Healthcare professionals trained on the use of the software	Under the direct supervision of a licensed healthcare practitioner, by trained operators	Similar
Use Location	In hospitals or facilities providing patient care	In a hospital or facility providing patient care	Same
Intended for real-time monitoring.	No	No	Same
Functional Equivalence			
Own storage of records or associated reports and documents	No	Yes	Different (See Substantial Equivalence Discussion below)
Search for, list and open ECG studies	Yes	Yes	Same
List and open other ECGs for the same patient	Yes	Yes	Same
View and print digitized ECG waveforms, discrete measurements, and diagnostic statements	Yes	Yes	Same

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Characteristic	New Device	Predicate Device	Similar / Different
View and print digitized waveforms using common display layouts	Yes	Yes	Same
Adjust displayed waveform gain and speed	Yes	Yes	Same
Measure intervals and amplitudes in digitized waveforms using onscreen calipers	Yes	Yes	Same
Filter displayed waveforms	Yes	Yes	Same
Serial presentation of ECGs for the same patient	Yes	Yes	Same
Algorithmic serial comparison with the first previous ECG for the same patient	No	Workstation: Yes Web Client: No	Same as predicate device's web client
Manual editing of discrete ECG measurements	Yes	Yes	Same
Algorithmic reanalysis of waveforms to quantify measurements and provide diagnostic statements	No	Workstation: Yes Web Client: No	Same as predicate device's web client
View, edit, print, and confirm diagnostic statements	Yes	Yes	Same
Embedded integration in an external application	Yes	Workstation: No Web Client: Yes	Same as predicate device's web client
Single sign-on access to device from within external application	Yes	Yes	Same
Manage user groups and authorizations centrally	Yes	Yes	Same
Comprehensive audit logs	Yes	Yes	Same
Technical Equivalence			
Software only	Yes	Yes	Same
HTML5 web client	Yes	Workstation: No Web Client: Yes	Same as predicate device's web client

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Characteristic	New Device	Predicate Device	Similar / Different
Access centrally stored records via TCP/IP network communication	Yes, using open standard DICOM protocols and data formats	Yes, using non-disclosed proprietary protocols and data formats	Different (See Substantial Equivalence Discussion below)
Secure network communication	Yes	Yes	Same
Externally facing DICOM interface	Yes	Yes	Same
Externally facing LDAP interface	Yes	Yes	Same
Externally facing HL7 interface	N/A	Yes	Subject device does not provide own storage

With the exception of own storage of records or associated reports and documents, further discussed below, the Predicate Device Comparison demonstrates that Cordiana Dx16's indications and intended use, functionality, and technological characteristics are the same or significantly similar to the predicate device, and especially its web client (marketed as "MUSE™ NX").

Substantial Equivalence Discussion

The predicate device provides its own storage of records in a central server, with which its Workstations and Web Clients communicate over a network using a non-disclosed proprietary protocol. Cordiana Dx16 relies on storage of records in a remote storage system, with which it communicates over a network using the open and standardized DICOM protocol.

Reliance on the DICOM standard for network communication with and storage of records in remote storage systems, such as Picture Archive and Communication Systems (PACS), is well defined, mature, and in wide use for a great number of different medical devices for acquisition and post processing in medical imaging. The DICOM standard furthermore includes comprehensive provisions for network communication and storage of records (including discrete measurements, text and digitized waveforms), reports and documents for cardiopulmonary diagnostics.

The demonstrated difference between Cordiana Dx16 and the predicate device is therefore neither critical to its intended use, nor does it raise different questions of safety and effectiveness, compared with the predicate device's proprietary network communication and own storage of records, when used as labeled.

Performance Testing

Non-clinical testing performed included software verification and validation, in compliance with IEC 62304 and IEC 62366-1, to ensure that Cordiana Dx16 meets design specifications and requirements. Unit and system level testing included assurance of interoperability with representative remote storage systems and accuracy of displayed waveforms and related information in a simulated user test environment.

Bench testing performed verified the Cordiana Dx16 display and measurement capabilities using sample cases based on technical characteristics and relevancy to the intended function of the Cordiana Dx16 application. In particular, the testing was performed to ensure user readability and quality on different supported browsers.

In all instances, the Cordiana Dx16 functioned as intended by the design requirements and the observed results demonstrated substantial equivalence with the predicate device.

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Performance Standards

There are no applicable FDA mandated performance standards for this device. However, Cordiana Medical Informatics AG's in-house standard operating procedures were used for the development of the software; these procedures conform to the following FDA recognized consensus standards:

- ISO 14971:2007 Medical devices — Application of risk management to medical devices
- IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices
- IEC 62304:2006 Medical device software — Software life cycle processes, as amended by IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes — Amendment 1

Querying, retrieving and storing records, reports and documents in a remote storage system comply with applicable provisions of the FDA recognized consensus standard:

- NEMA PS 3.1 – 3.20 (2016): Digital Imaging and Communications in Medicine (DICOM)

Furthermore, Cordiana Dx16's requirements and design specifications were defined to comply with the applicable ECG Report and Filter requirements of the FDA recognized consensus standard:

- IEC 60601-2-25:2011 Medical electrical equipment — Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

Conclusion

As a result of the product's technical characteristics, performance testing activities, and standards compliance, Cordiana Medical Informatics AG considers Cordiana Dx16 to be as safe, as effective, and performance is substantially equivalent to the predicate device.