Konica Minolta Healthcare Americas, Inc.
℅ Mr. Scott Blood
Director of Regulatory Services
MEDicept, Inc.
200 Homer Avenue
ASHLAND MA 01721

December 10, 2021

Re: K203743
Trade/Device Name: EXA™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 11, 2021
Received: November 12, 2021

Dear Mr. Blood:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K203743

Device Name
EXA™

Indications for Use *(Describe)*
EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used.

Typical users of this system are trained professionals, nurses, and technicians.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92. This Summary was prepared on December 21, 2020.

1. Submitter's Information

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Ashland, MA 01721
Scott Blood
sblood@medicept.com
978.729.5978

2. Device Identification

Proprietary – Tradename: EXA™

Classification Name: Picture Archiving and Communications System

Medical imaging management and processing system

Product Code: LLZ, Class II

Regulation: 892.2050

Common/Usual Name: PACS System

3. Legally Marketed Predicate Device

EXA™ - K142919

The predicate has not been subject to a design-related recall.

4. Indications for Use (Proposed Device)

EXA™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.

5. Device Description

EXA™ is a software suite of web based PACS applications that was developed specifically to handle the DICOM protocol, for both transmitting and viewing DICOM images and data elements. The applications were developed so that access to the PACS can occur from any Microsoft Windows computer with internet capabilities and offer an interface that users find to be quite intuitive after some initial learning. (Not intended for use on mobile devices) The EXA™ applications deal with all manner of DICOM images and modalities, including MR, CT, CR, US, MG and many others. These images can be viewed, annotated, transmitted to other facilities, printed, animated and stored using the EXA™ PACS suite.

6. Substantial Equivalence Discussion

The results of software validations after each version update that the new version of software is as safe and effective as our predicate software device.

Characteristic	EXA™ - K142919 (Predicate device)	EXA™ - This submission (Subject device)
FDA Product Code	LLZ	LLZ
Indications for Use	EXA™ is a software device that receives digital images and data from	EXA™ is a software device that receives digital images and data from

Characteristic	EXA™ - K142919 (Predicate device)	EXA™ - This submission (Subject device)
	various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.	various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used. Typical users of this system are trained professionals, nurses, and technicians.
Configuration	Submission was for software only	Same
Film Digitizer	No film digitizer is part of the system	No film digitizer is part of the system
DICOM	DICOM 3.0	DICOM 3.0
Compression	Wavelet/JPEG2000	JPEG2000 lossless
Improvements to Perform Imaging Work	YES • The ability to rotate of MIP in MPR mode was the added function. • Verify Multiplanar reconstruction	YES • Added ability to scan images at Order Level • Added ability to draw Quick3D Spine label annotation on axial images • Added option in Viewer to export images to AVI format
Expanded GUI Interface to Integrate More Effectively with the web	YES • Expanded GUI Interface for users changes to allow client EXA to function with Web	YES • SDE Report formatting in GUI
Language Capability	YES • Ability to use multilingual interface to client's operating system (i.e foreign country multi-language translation from English).	YES • Improved code to better handle date formats in various languages

Characteristic	EXA™ - K142919 (Predicate device)	EXA™ - This submission (Subject device)
	• Allows interpretation of Spanish and Portuguese	• Internationalized program error codes to prepare for localization
Worklist Expansion • **Web Worklist** • **Client Worklist**	YES • Web Work list- includes most of the advanced study list features and the entire Image Viewing features, but cannot create Patient CDs or Import images and scanned documents. Verify Client Worklist- Includes all the advanced Study List and Image • Viewing features mentioned above. Available modules in the client worklist provide the following: Sending and Receiving images over phone line, local area networks and the Internet. Included in this includes DICOM transmission/receive	YES • Change worklist column grid to use viewer globe icon & add approved report link, Add a new approved report column to 'My Exams' and 'Group Exams' worklist allowing a user to view the approved report if one exists • Add a new column, Study Status, to all worklist grids on physician portal, Add a new Study Status column that shows the study status of each study. It should use a dropdown for filtering. Add the Study Status column as an option in the filter manager • Add Export function to Worklist - Add the ability to Export search/filtered results from the main studies Worklist
Verify PACS Backend – DICOM Improvements	YES • Ability to add clarity to DICOM images has been allowed	YES • The EXA PACS/RIS viewer now supports vendor-specific names for 2D synthesized views (CView, V-Preview,and Insight View). • Improved code-level image request handling to increase performance of the EXA PACS/RIS viewer
Improvements to Panel Guide PACS – UAI Multifunctional Interface	YES	NO
Module Updates	YES • Peer Review-Allows a radiologist to review a report from a second radiologist • Exam Report Module functions per specification	NO
Computer	PC	Same
Power Source	AC Line (PC Required)	Same

The EXA software was developed per the following standards:

- IEC 62304:2015 Medical Device software - Software life cycle process
- ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices

This EXA software premarket submarket submission was prepared using the following CDRH guidance documents:

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014
- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11,2005 Medical Devices, Document issued on: May 11, 2005

7. Conclusion

Based upon fact that the Viztek EXA™ and the Konica Minolta Healthcare Americas EXA™ is the same software, and the version updates made to the EXA software did not change the Intended Use of the software, it can be concluded the Konica Minolta Healthcare Americas EXA is substantially equivalent to the identified predicate device Viztek EXA in terms of intended use, safety and effectiveness. Software validations for each version update demonstrate that the specifications and performance of the device is as functional and effective as the legally marketed predicate device. Therefore, it is concluded that this system is substantially equivalent to the legally marketed predicate device.