Change Healthcare Canada Company
℅ Chester Mccoy
VP, QA/RA & Chief Quality Officer
10711 Cambie Road
Richmond, BC V6X 3GS
CANADA

July 20, 2021

Re: K210719
Trade/Device Name: Change Healthcare Anatomical AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: June 23, 2021
Received: June 24, 2021

Dear Chester Mccoy:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210719

Device Name
Change Healthcare Anatomical AI

Indications for Use *(Describe)*

Change Healthcare Anatomical AI is intended to analyze pixel data from CT or MR images to create comprehensive anatomic descriptors for export to integrated healthcare systems.

This supplements traditional methods used for the selection, presentation or analysis of image based medical data. The application is intended to enable physicians, or other healthcare providers as well as integrated healthcare systems to rapidly identify images, series, and/ or studies of interest.

Change Healthcare Anatomical AI is not indicated for patients under the age of 18 years old.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 5: 510 (k) Summary

The Company's 510(k) Summary of Change Healthcare Anatomical AI (K210719), prepared in accordance with 21 CFR 807.92(C), is provided on the following page.

510(k) SUMMARY

Change Healthcare Anatomical AI

1. Introduction and Administrative Information

This 510(k) Summary provides a high-level summary of the contents of the Change Healthcare Anatomical AI Premarket Notification (510(k)), including a comparison of Change Healthcare Anatomical AI to existing legally marketed medical device.

This Premarket Notification (510(k)) Summary contains no confidential or trade secret information. For additional information, please contact the Establishment's contact listed below.
This summary was prepared on March 9, 2021.

1.1. Submitter

Submitter	Change Healthcare Canada Company
Submitter Address	10711 Cambie Road Richmond, B.C. Canada, V6X 3G5
Submitter Phone	(604) 279-5422
Submitter Website	www.changehealthcare.com
Establishment Number	8022257
Establishment Contact	Chester McCoy
Contact Title	VP, QA/RA & Chief Quality Officer
Contact Phone	(404) 338-2088
Contact Email	chester.mccoy@changehealthcare.com

1.2. Device Identification

Proprietary Name(s):	Change Healthcare Anatomical AI
Common/ Usual Name:	Automated Radiological Image Processing Software

1.3. Device Classification

Device classification:	Class II
Regulation Number:	21 CFR 892.2050
Classification Product Code:	QIH
Classification Name:	Automated Radiological Image Processing Software
Regulation Description:	Medical image management and processing system

1.4. Predicate Device Identification

Proprietary Name(s):	AquariusAPS Server
510(k) Number:	K061214
Applicant:	TeraRecon, Inc.

No reference devices were used in this submission.

2. Indications for Use and Device Description

2.1. Indications for Use

Change Healthcare Anatomical AI is intended to analyze pixel data from CT or MR images to create comprehensive anatomic descriptors for export to integrated healthcare systems.

This supplements traditional methods used for the selection, presentation or analysis of image based medical data. The application is intended to enable physicians, or other healthcare providers as well as integrated healthcare systems to rapidly identify images, series, and / or studies of interest.

Change Healthcare Anatomical AI is not indicated for patients under the age of 18 years old.

2.2. Device Description

Change Healthcare Anatomical AI is a standalone image processing software application that analyzes CT and MR DICOM images to associate anatomic regions with images and exports the derived information for use in integrated healthcare systems. These anatomic descriptors can be applied by integrated applications to categorize anatomy from a patient's CT or MR image, series, or study.

The device communicates via Application Programmable Interfaces (APIs) which allow for receiving DICOM images and returning inference results. The algorithm produces a JSON file which contains results of the analysis for each image and study with the corresponding identified body regions.

Change Healthcare Anatomical AI works in parallel to and in conjunction with the standard of care workflow. The device does not alter the original medical image in any way. The anatomic descriptors are used as supplemental metadata for a patient's imaging study.

Change Healthcare Anatomical AI contains the following core components:

<u>API endpoints</u>
The device uses API endpoints which allow for receiving DICOM images and returning results.

Following receipt of an image, the device performs data validation to ensure appropriateness and compatibility for the algorithm. If the validation fails and the image cannot be processed, an error is returned with the corresponding code and description.

<u>AI algorithm</u>
After validation, the algorithm analyzes the CT or MR image pixel data and generates the anatomic descriptors.

Study results aggregator

The results of the analysis for each image in a study are aggregated and returned to the integrated system.

Data store

The results of the inference for each analyzed image are maintained in a persistent data store. The results are stored by the algorithm inference model and retrieved by the study results aggregation component.

3. Comparison of Technological Characteristics with the Predicate Device

With respect to technological characteristics, Change Healthcare Anatomical AI is substantially equivalent to the predicate device. A comparison of the proposed device to the currently marketed predicate device is provided in the table below:

Description	**Subject Device**	**Predicate Device**
Device proprietary name	Change Healthcare Anatomical AI	AquariusAPS Server
Manufacturer	Change Healthcare Canada Company	TeraRecon, Inc.
510(k) Number	K210719	K061214
Classification	Class II	Class II
Product Code	QIH	LLZ
Regulatory Number	892.2050	892.2050
Platform	Change Healthcare Enterprise Imaging Network (EIN) cloud platform	TeraRecon
Intended for use in primary diagnostic workflow	Yes	Yes
Process DICOM images	Yes	Yes
Identify locations of anatomical structures	Abdomen, breast (MR only), calf, chest, elbow, foot, forearm, hand, head, arm, knee, neck, pelvis, shoulder, spine cervical, spine thoracic, spine lumbar, and thigh	Brain, Heart, Heart Vasculature, Liver, Lung
Modalities supported for identification of anatomical structures	CT and MR	CT

Description	Subject Device	Predicate Device
Algorithm	Machine learning based algorithm (non-adaptive)	Image processing based algorithm
Manual review of identified anatomical structures	Yes	Yes
Can be used to navigate to a study based on an identified anatomical structure	Yes	Yes
Performing actions based on DICOM and other data identified from the DICOM image set	Yes	Yes

4. Performance Data

4.1. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device is considered as a Moderate Level of Concern software medical device, since a failure or latent design flaw could indirectly result in minor injury to the patient through incorrect or delayed information through the action of a care provider.

Verification and Validation Plans and Protocols have been executed to ensure adequate testing of all defined product design requirements and specifications and the device performs as intended. Software verification testing assessed the performance of the software's anatomical structure detection function, performance characteristics of the algorithm including image-level accuracy, risk management, and overall functional performance.

A retrospective study was designed to assess the subject device accuracy. For each modality, three databases were built for the AI model training, validation, and testing, with a balanced distribution of studies per body region. By design, no repeat or temporal studies were allowed in the validation and test databases.

The test databases originated from a different healthcare system. The de-identified datasets were gathered from multiple centers to reduce bias due to demographics, scanner manufacturer and

acquisition protocols. 27 institutions from primary care hospitals, community hospitals and imaging centers contributed to the test datasets. The data included cases of all genders in equal proportions and subjects aging from 18 years old and above.

This all-comers study was designed with the intent to be as inclusive as possible and clinically relevant. All randomly selected patients from 18 years old and above were included in the study irrespective of their demographic or comorbidities. The same inclusive approach was followed for clinical protocols.

The accuracy results were evaluated according to patient demographics, healthcare institution, and other confounding imaging factors such as scanner manufacturer, presence of contrast, slice thickness, MR sequence, and CT kernel.

Test Summary Reports have been created to evaluate the acceptability of test results and all applicable verification and validation activities and records have been completed to ensure safety and effectiveness of the device.

Change Healthcare Anatomical AI adheres to the cybersecurity requirements as defined by the FDA Guidance "*Content of Premarket Submissions for Management for Cybersecurity in Medical Devices*," by implementing cybersecurity controls to protect data in use, in transit or at rest for the components in the product.

4.2. Conformance Standards

There are no applicable FDA required performance standards for this device. However, voluntary standards have been utilized in the design and development of the software. The following FDA recognized consensus standards were used:

- ISO 14971:2007 – Medical devices – Application of risk management to medical devices
- ISO 15223-1:2016 - Medical devices – Symbols to be used with medical devices labels, labeling, and information to be supplied – Part 1: General requirements
- IEC 62304:2015 – Medical device software – Software life cycle processes
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
- NEMA PS 3.1-3.20 (2016) – Digital Imaging and Communications in Medicine (DICOM) set

5. Conclusion

Change Healthcare Anatomical AI is substantially equivalent to the identified predicate device AquariusAPS Server (K061214). Specifically, Change Healthcare Anatomical AI has the similar indications for use and technological characteristics compared to the previously cleared predicate device.

The minor differences in the technological characteristics of Change Healthcare Anatomical AI and AquariusAPS Server, its predicate device, including the platform where the device is installed, identification of additional anatomical structures, additional modalities supported and algorithm type, these minor differences do not raise new issues of safety or effectiveness. The performance tests have been completed and successfully support the device performance. Therefore, Change Healthcare Anatomical AI is substantially equivalent to the predicate device.