July 13, 2023

Siemens Medical Soultions USA, Inc.
% Milind Dhamankar
Clinical Affairs Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19335

Re: K231351
Trade/Device Name: Chondral Quant
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, LNH
Dated: April 28, 2023
Received: May 9, 2023

Dear Milind Dhamankar:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K231351

Device Name

Chondral Quant

Indications for Use *(Describe)*
Chondral Quant is a musculoskeletal post-processing software application that allows assessment of knee cartilage condition based on Magnetic Resonance Imaging (MRI).

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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SIEMENS Healthineers

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

1. General Information

Establishment:

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared:

July 12, 2023

Manufacturer:

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Registration Number: 3002808157

2. Contact Information

Milind Dhamankar
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3. Device Name and Classification

Device/ Trade name:	Chondral Quant
Classification Name:	System, Image Processing, Radiological Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	II
Product Code:	Primary: LLZ Secondary: LNH

4. Legally Marketed Predicate Device[1]

Trade name:	syngo.MR Applications – syngo.MR Brain Morphometry
510(k) Number:	K182904
Classification Name:	Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	II
Product Code:	Primary: LLZ Secondary: LNH

5. Intended Use / Indications for Use

Chondral Quant is a musculoskeletal post-processing software application that allows assessment of knee cartilage condition based on Magnetic Resonance Imaging (MRI).

6. Device Description

The medical device Chondral Quant, software version VA10A, is a musculoskeletal post-processing application that allows evaluating the status of knee cartilage based on Magnetic Resonance Imaging (MRI).

The software is part of the syngo OpenApps framework and can be used from within syngo.via like any other syngo.via workflow.

Version VA10A is the initial version of this medical device.

Chondral Quant processes a morphological 3D series of the knee joint and performs an automated segmentation of the knee's cartilage. The segmentation may be modified by the user. Chondral Quant will also perform a sub-segmentation of the knee cartilage. Chondral Quant additionally performs volumetry and thickness calculation on the segmented areas. Optionally, it is possible to provide a parametric map as secondary input to Chondral Quant. Commonly, this will be a T2 or T2* map. Chondral Quant will perform a registration of the morphological image and the parametric map and transfer the segmentation to the parametric map.

A statistical evaluation of the mapping results for the 21 sub zones will be additionally provided in this case.

All output will be provided in the form of a table showing statistical evaluation of the assessment (volume and mean, median and standard deviation of thickness and mapping results for every region). Additionally, Chondral Quant will generate output maps (segmentation map, cartilage thickness map) and 3D models of the segmented cartilage

[1] The predicate device has not been subject to a design-related recall.

(zone model and thickness model). Finally, a PDF report containing the table values and the 3D models will be generated as output.

Alternatively, the application Chondral Quant may also be executed in a "PACS-ready" mode, i.e. fully-automated and without user interaction. The results will be sent to PACS automatically. In this case the series names will be marked with a prefix "AUTO_GENERATED" for a clear indication of the automatic mode.

The subject device, Chondral Quant with software VA10A, consists of new and modified features that are similar to what is currently offered on the predicate device. The subject device includes the following modifications in comparison to the predicate device: new body region compared to predicate device:

- Automatic segmentation and volumetry of the cartilage
- Thickness calculation

7. Substantial Equivalence

Chondral Quant with software version VA10A is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
syngo.MR Applications – syngo.MR Brain Morphometry	K182904 - July 5, 2019.	LLZ, LNH	Siemens Healthcare GmbH

The following summary comparison provides an overview of changes Chondral Quant with software VA10A compared to the predicate device. Hardware comparison is not applicable as Chondral Quant is a SW-only device.

	Subject Device **Chondral Quant VA10A**	**Predicate Device** ***syngo*.MR Applications - *syngo*.MR Brain Morphometry (K182904)**
Intended Purpose	Chondral Quant is a musculoskeletal post-processing software application that allows assessment of knee cartilage condition based on Magnetic Resonance Imaging (MRI). Chondral Quant processes a morphological 3D series of the knee joint and performs an automated segmentation of the knee's cartilage. Chondral Quant additionally performs volumetry and thickness calculation on the segmented areas.	*syngo*.MR Applications is a *syngo* based postacquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra. syngo.MR Brain Morphometry offers a comprehensive package for the automatic calculation of the volume properties of different brain structures using MPRAGE datasets, which are typically acquired for a typical MR examination of the head.
Features / Functionalities		

Integration into general *syngo*.via workflow concept	Yes	Yes
Support Images Modalities	MR	MR
Data Acquisition Protocol	MRI Image Series	MRI Image Series
Body Region	Knee	Brain
Clinical Use Case	Automatic segmentation and volumetry of the cartilage	Automatic segmentation and volumetry of different brain structures
Segmentation algorithm		
Template registration	Yes Atlas-based initialization for the bone segmentation	Yes Free tissue classification
Bias field correction	Yes Preprocessing bias field correction	Yes
Skull-stripping	No	Yes
Tissue classification	Yes Cartilage segmentation	Yes Brain tissue classification
Segmentation quality check	No	Yes
Volumetry	Yes Volume calculation	Yes Lobe-wise GM volumes
Thickness calculation	Yes	No
3D Segmentation	Yes	Yes
Clinical sub-regions	21 clinical sub-regions	57 clinical sub-regions
Output	- DICOM - Maps and statistical evaluations	
Workflow	- PACS-ready without user interaction - Interactive mode (manual changes by user possible)	
Normative References / Deviation Maps	No	Yes

8. Technological Characteristics

The subject device Chondral Quant with software version VA10A is substantially equivalent to the predicate device with regard to the operational environment, programming language, operating system and performance.

The subject device conforms to the standard for medical device software (IEC 62304).

9. Nonclinical Tests

The following performance testing was conducted on the subject devices.

Performance Test	Tested Software	Source/Rationale for test
Subsystem Verification Report	Chondral Quant VA10A	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Solution Validation Summary Report		

Algorithm	Cases	Equipment:
Training data:	more than 31	3T MRI systems
Testing data:	more than 100 cases	3T MRI systems
	more than 11 cases	7T MRI systems
	more than 9 cases	1.5T MRI systems

Non-clinical tests such as unit test, integration testing, and system test are passed.

The system test results indicate that open defects were identified which had no impact on safety and effectiveness of Chondral Quant with software version VA10A.

10. Clinical Tests / Publications

No clinical tests were conducted for the subject device.

Clinical publications and other support documents were referenced to provide information on the use, testing and validation of the Subject Device.

No animal testing has been performed.

11. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971, to identify and provide mitigation of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthcare GmbH adheres to recognized and established industry standards, to minimize hazards. Furthermore, the device is intended for healthcare professionals.

Chondral Quant with software version VA10A conforms to the following standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
5-125	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Third Edition 2019-12	ISO
5-114	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1:2015, Edition 1.0 2015-02	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC

12. Conclusion as to Substantial Equivalence

The extensive testing of Chondral Quant with software version VA10A has been successfully completed. All risk mitigations, as identified in the Risk Analysis and all relevant SSRS/FS requirements for Chondral Quant with software version VA10A have been tested and verified successfully.

Verification and validation of the product within the meaning of the Quality System Regulation (21 CFR § 820.30) have been performed by trained personnel. Chondral Quant with software version VA10A has been found to be validated for its intended use.

Indications for Use for subject device is different compared to the predicate device, however the intended use is the same. syngo.via is the hosting platform for both the subject device and the predicate device. Both the devices are integrated into the already cleared and marketed general syngo.via workflow concept. Chondral Quant processes a morphological 3D series of the knee joint and performs an automated segmentation of the knee's cartilage. Chondral Quant additionally performs volumetry and thickness calculation on the segmented areas and optionally performs registration of a parametric map while syngo.MR Brain Morphometry processes a morphological 3D data series and offers a comprehensive package for the automatic calculation of the volume properties of different brain structures.

The difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device.

Therefore, it is Siemens' opinion that the safety and effectiveness of the subject device have been fully verified by objective evidence, and that the subject device performs as safely and effectively as the predicate device (K182904) and the subject device is substantially equivalent to the predicate device.