Ricoh USA, Inc.
℅ Scott Brewer
Director, Regulatory Affairs and Quality, Additive Manufacturing
5575 Venture Drive, Unit A
PARMA OH 44130

May 2, 2023

Re: K230119
Trade/Device Name: 3D Anatomic Model
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 28, 2023
Received: March 29, 2023

Dear Scott Brewer:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K230119

Device Name
3D Anatomic Model

Indications for Use *(Describe)*

Ricoh 3D Anatomic Models are intended as physical replicas of patient anatomy to be used for diagnostic purposes in the fields of craniomaxillofacial, orthopedic, cardiovascular, neurological, gastrointestinal, genitourinary, and breast applications. The Anatomic Models are based on DICOM imaging information from a medical scanner and output files from FDA cleared software intended for the creation and output of digital files suitable for the fabrication of physical replicas. The models should be used in conjunction with other diagnostic tools and expert clinical judgement.

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.

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510(k) SUMMARY

K230119

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

I. SUBMITTER

Ricoh USA, Inc.
5575 Venture Drive Unit A
Parma, Ohio | USA | 44130
Tel: +1.954.648.5680
Email: Gary.Turner@RicohUSA.com

Contact Person: Scott Brewer
Date Prepared: January 16, 2023

II. DEVICE

Name of Device:	3D Anatomic Model
Classification Name:	Radiological Image Processing
Regulation:	System 21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	LLZ

III. PREDICATE & REFERENCE DEVICES

Predicate Manufacturer:	Ricoh USA, Inc.
Predicate Trade Name:	3D Anatomic Models
Predicate 510(k):	K220205

IV. DEVICE DESCRIPTION

The subject device, each “Ricoh 3D Anatomic Model,” is a patient-specific physical replica of an anatomic structure or site, produced via additive manufacturing from a user generated 3D print file. The input 3D print file is created from medical images in DICOM format that have been segmented to a specific region of interest within an FDA cleared application, IBM iConnect Access (K203104). The input 3D print file is then transferred to Ricoh for production and delivery of the physical replica.

V. INDICATIONS FOR USE

Ricoh 3D Anatomic Models are intended as physical replicas of patient anatomy to be used for diagnostic purposes in the fields of craniomaxillofacial, orthopedic, cardiovascular, neurological, gastrointestinal, genitourinary, and breast applications. The Anatomic Models are based on DICOM imaging information from a medical scanner and output files from FDA cleared software intended for the creation and output of digital files suitable for the fabrication of physical replicas. The models should be used in conjunction with other diagnostic tools and expert clinical judgement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

	Anatomic Models (Subject Device)	Ricoh 3D Anatomic Models K220205	Comments on SE
Trade Name	Anatomic Models, Ricoh 3D	Anatomic Models, Ricoh 3D	-
Common Name	Image processing system	Image processing system	Same
Classification Name	System, Image processing, Radiological	System, Image processing, Radiological	Same
Classification	LLZ	LLZ	Same
Product Code	892.2050	892.2050	Same
Indications for Use	Ricoh 3D Anatomic Models are intended as physical replicas of patient anatomy to be used for diagnostic purposes in the fields of craniomaxillofacial, orthopedic, cardiovascular, neurological, gastrointestinal, genitourinary, and breast applications. The Anatomic Models are based on DICOM imaging information from a medical scanner and output files from FDA cleared software intended for the creation and output of digital files suitable for the fabrication of physical replicas. The models should be used in conjunction with other diagnostic tools and expert clinical judgement.	Ricoh 3D Anatomic Models are intended as physical replicas of patient anatomy to be used for diagnostic purposes in the fields of craniomaxillofacial and orthopedic applications. The Anatomic Models are based on DICOM imaging information from a medical scanner and output files from FDA cleared software intended for the creation and output of digital files suitable for the fabrication of physical replicas. The models should be used in conjunction with other diagnostic tools and expert clinical judgement.	The indications for use of the subject device expand the scope of anatomic regions from those listed for the predicate device. Expanded applications include cardiovascular, neurological, gastrointestinal, genitourinary, and breast.
Design (key components/features)	The Ricoh 3D Anatomical Models are produced from a 3D print file. The 3D print file is imported from a Class II medical device, which allows for advanced image segmentation and editing tools for the purpose of creating digital 3D anatomical models. Once the 3D print file is imported, the surgical team, radiological team (segmentation team) and Ricoh production team can: • Communicate about project needs/scope,	The Ricoh 3D Anatomical Models are produced from a 3D print file. The 3D print file is imported from a Class II medical device, which allows for advanced image segmentation and editing tools for the purpose of creating digital 3D anatomical models. Once the 3D print file is imported, the surgical team, radiological team (segmentation team) and Ricoh production team can: • Communicate about project needs/scope,	Same

	Anatomic Models (Subject Device)	Ricoh 3D Anatomic Models K220205	Comments on SE
	establish/track project timelines, • Approve final STL file for fabrication Under the direction of the clinical user, the Ricoh Biomedical Engineering team will generate a printable anatomic model. Once final approval of the model is achieved from the clinical user, the anatomical model will be printed, post-processed, and undergo a quality validation process. After inspection and approval, the anatomical model is labeled and distributed to the customer.	establish/track project timelines, • Approve final STL file for fabrication Under the direction of the clinical user, the Ricoh Biomedical Engineering team will generate a printable anatomic model. Once final approval of the model is achieved from the clinical user, the anatomical model will be printed, post-processed, and undergo a quality validation process. After inspection and approval, the anatomical model is labeled and distributed to the customer.	
Performance Testing	• Geometric accuracy of the physical replicas	• Geometric accuracy of the physical replicas	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Validation Testing

Validation testing included assessment of the workflow from input digital 3D file to output physical replica. Similar to the predicate device, the geometric accuracy of printed physical models was assessed via bench testing. Testing showed that the physical models can be printed accurately at less than 1mm mean deviation when compared against the input digital 3D file, and all clinically relevant acceptance criteria were met.

Shipping Validation

Simulated distribution and handling testing was performed to assess the packaging for Ricoh 3D Anatomic Models. Testing showed that the packaging adequately protects the product from damage throughout the distribution process.

VIII. CONCLUSIONS

A comparison of intended use and technological characteristics combined with performance data demonstrates that Ricoh 3D Anatomical Model is substantially equivalent to the predicate device.