Axial Medical Printing Limited
℅ Sujith Shetty
Executive Vice President
Maxis Medical LLC
3031 Tisch Way, Suite 1010
San Jose, California 95128

January 24, 2024

Re: K231607
Trade/Device Name: Axial3D Cloud Segmentation Service
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 28, 2023
Received: January 2, 2024

Dear Sujith Shetty:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231607

Device Name
Axial3D Cloud Segmentation Service

Indications for Use *(Describe)*

Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation Framework for the transfer of DICOM imaging information from a medical scanner to an output file, which can be used for the fabrication of physical replicas of the output file using additive manufacturing methods.

The output file or physical replica can be used for treatment planning and/or diagnostic purposes in the field of orthopedic, maxillofacial, and cardiovascular applications in adults. The output file or physical replica may also be used for pediatrics between the ages of 12 and 21 years of age in cardiovascular applications.

Axial3D Cloud Segmentation Service should be used with other diagnostic tools and expert clinical judgment.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF 807.92.

510 (k) number: K231607

Applicant Information

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Belfast
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United Kingdom
Tel: +44 (0)28 90183590

Contact Person

Joanne Flatley, QA/RA Lead

Device Information

Trade Name	Axial3D Cloud Segmentation Service
Common Name	Medical image management and processing system
Classification number	892.2050
Regulatory Class	II
Product Code	LLZ

Predicate Device

Table 1 - Predicate Device

Name	Manufacturer	510(k)#
Axial3D	Axial Medical Printing Limited	K221511

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

Device Description

Axial3D Cloud Segmentation Service is a secure, highly available cloud-based image processing, segmentation, and 3D modelling framework for the transfer of imaging information either as a digital file or as a 3D printed physical model.

Indications for Use

Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation framework for the transfer of DICOM imaging information from a medical scanner to an output file, which can be used for the fabrication of physical replicas of the output file using additive manufacturing methods.

The output file or physical replica can be used for treatment planning and/or diagnostic purposes in the field of orthopedic, maxillofacial, and cardiovascular applications in adults. The output file or physical replica may also be used for pediatrics between the ages of 12 and 21 years of age in cardiovascular applications.

Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.

Comparison of Intended Use to Predicate Devices

Table 2 – Predicate Device Comparison: Intended Use

Attribute	Axial3D Cloud Segmentation Service (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Comparison
Device Manufacturer	Axial Medical Printing Limited	Axial Medical Printing Limited	Equivalent
Device Name	Axial3D Cloud Segmentation Service	Axial3D Cloud Segmentation Service	Equivalent
Device Trade or Proprietary Name	Axial3D Cloud Segmentation Service	Axial3D Cloud Segmentation Service	Equivalent
510(k) Number	K231607	K221511	N/A
Device Regulation Name:	Medical image management and processing system	Medical image management and processing system	Equivalent
Device Regulation Number:	21 CFR 892.2050	21 CFR 892.2050	Equivalent
Device Product Code:	LLZ	LLZ	Equivalent
Device Classification FDA:	Class II	Class II	Equivalent
Indication for Use	Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation framework for the transfer of DICOM imaging information from a medical scanner to an output file, which can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The output file or physical replica can be used for treatment planning and/or diagnostic purposes in the field of orthopedic, maxillofacial, and cardiovascular applications in adults. The output file or physical replica may also be used for pediatrics between the	Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. The Axial3D Cloud Segmentation Service output file can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The output file or physical replica can be used for treatment planning. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial	Similar. The proposed device includes specifications for , orthopedic, maxillofacial, and cardiovascular applications for adults and children greater than 12 years old and in cardiovascular applications for children greater than 2 months of age population in which 3D models can be provided for based on clinical imaging.

Attribute	Axial3D Cloud Segmentation Service (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Comparison
	ages of 12 and 21 years of age in cardiovascular applications. Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.	and cardiovascular applications. Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.	
Intended Use	Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation framework for the transfer of DICOM imaging information from a medical scanner to an output file, which can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The output file or physical replica can be used for treatment planning and/or diagnostic purposes in the field of orthopedic, maxillofacial, and cardiovascular applications in adults. The output file or physical replica may also be used for pediatrics between the ages of 12 and 21 years of age in cardiovascular applications. Axial3D Cloud Segmentation Service should be used in	Axial3D Cloud Segmentation Service is intended for use as a cloud-based service and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. The Axial3D Cloud Segmentation Service output file can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The output file or physical replica can be used for treatment planning. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.	Similar. The proposed device includes specifications for , orthopedic, maxillofacial, and cardiovascular applications for adults and children greater than 12 years old and in cardiovascular applications for children greater than 2 months of age population in which 3D models can be provided for based on clinical imaging.

Attribute	Axial3D Cloud Segmentation Service (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Comparison
	conjunction with other diagnostic tools and expert clinical judgment. .		
Target Populate	Adult for all indications children 12 to 21 for cardiovascular indication	Adult	Similar
Method of Use	Used in conjunction with other diagnostic tools and expert clinical judgement.	Used in conjunction with other diagnostic tools and expert clinical judgement.	Equivalent
Image Modality	Computed tomograghy (CT), CT Angiography (CTA)	Computed tomograghy (CT), CT Angiography (CTA)	Equivalent
Environment	Hospital	Hospital	Equivalent
OTC or Prescription Device	Prescription Use	Prescription Use	Equivalent
Level of Concern	Moderate	Moderate	Equivalent
V&V	Complies with FDA Guidance Requirement	Complies with FDA Guidance Requirement	Equivalent

Comparison of Technological Characteristics to the Predicate Device and Reference Device

Table 3- Predicate Comparison: Technology

Attribute	Axial3D Cloud Segmentation Service (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Comparison
Method of Use	software interface	software interface	Equivalent
Computer Platform and Operating System	Internet Explorer 11 or equivalent	Internet Explorer 11 or equivalent	Equivalent

Attribute	Axial3D Cloud Segmentation Service (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Comparison
Supported Modalities	CT and CTA	CT and CTA	Equivalent
Image registration	Yes	Yes	Equivalent
Segmentation Features	A combination of automated tools with smart editing tools	A combination of automated tools with smart editing tools	Equivalent
View Manipulation and Volume Rendering	Yes	Yes	Equivalent
Regions and Volumes of Interest (ROI)	• Orthopedic • Maxillofacial • Cardiovascular	• Orthopedic • Maxillofacial • Cardiovascular	Equivalent
Region/volume of interest measurements and size measurements	Yes	Yes	Equivalent
Region/Volume Quantification	Yes	Yes	Equivalent

Performance Data

Nonclinical testing

Axial3D performed software design verification and validation testing on all three software components of the device and the software documentation for a Moderate Level of Concern software in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2015.

Axial3D has conducted software verification and validation, in accordance with the FDA guidance, General Principles of Software Validation; Final Guidance for Industry and FDA Staff, issued on January 11, 2002. All software requirements and risk analysis have been successfully verified and traced.

Axial3D Cloud Segmentation Service device has been validated for its intended use to determine substantial equivalence to the predicate device. Measurement accuracy and comparisons were performed and confirmed to be within specification of +/- .7mm.

Validation of printing of physical replica models was performed and demonstrated to be accurate when using any of the compatible printers.

Conclusions:

The Axial3D Cloud Segmentation Service with its expanded indication for use to include, orthopedic, maxillofacial, and cardiovascular cases in adults and children

greater than 12 years old is substantially equivalent to the predicate device cleared under K221511.

The technological aspects of the device have not changed from the original 510(k) approval. Validation of the printers and 3D model process has been performed and no safety or efficacy concerns are changed by the expanded indication for use.