Axial Medical Printing Limited
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

June 23, 2022

Re: K221511
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: May 23, 2022
Received: May 24, 2022

Dear Prithul Bom:

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 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)*
K221511

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 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.

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.

Axial Medical Printing Limited
Traditional 510(k)
For Axial3D Cloud Segmentation Service

510(k) Summary K221511

Submitters Contact Information

Submitter's Name: Axial Medical Printing Limited
17A Ormeau Avenue
Belfast
BT2 8HD
United Kingdom
Tel: +44 (0)28 90183590

Name of Contact Person

Jenna McGarry, QA/RA Manager

Date of submission

25th February 2022

Subject Device Name

Device Trade Name: Axial3D Cloud Segmentation Service

Device Common Name: Axial3D Cloud Segmentation Service

Classification Name: System, Image Processing, Radiological (21CFR 892.2050, Product Code LLZ)

Identification of Legally Marketed Predicate Device

The Axial Medical Printing Limited Axial3D Cloud Segmentation Service is substantially equivalent to the following:

Predicate Device

Manufacturer: Materialse NV

Trade Name: Mimics InPrint

Common Name: Mimics InPrint

Axial Medical Printing Limited
Traditional 510(k)
For Axial3D Cloud Segmentation Service

Classification Name: System, Image Processing, Radiological (21CFR 892.2050, Product Code LLZ)

510(k) Number: K173619

Device Description

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

Axial3D Cloud Segmentation Service is made up of a number of component parts, which allow the production of patient-specific 1:1 scale replica models, either as a digital file or as a 3D printed physical model.

Intended Use/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.

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.

Comparison between Proposed Device and Predicate Device

Product Details	New Device:	Proposed Predicate Device:	Comment:
Device Manufacturer	Axial Medical Printing Limited	Materialise N.V.	N/A
Device Name	Axial3D Cloud Segmentation Service	Mimics inPrint	N/A
Device Trade or Proprietary Name	Axial3D Cloud Segmentation Service	Mimics inPrint	N/A
510(k) Number	TBC	K173619	N/A

Device Regulation Name:	Medical Image Management and Processing System	Picture archiving and communications system	The proposed device and predicate devices are identical
Device Regulation Number:	21 CFR 892.2050	21 CFR 892.2050	The proposed device and predicate devices are identical
Device Product Code:	LLZ	LLZ	The proposed device and predicate devices are identical
Device Classification FDA:	Class II	Class II	The proposed device and predicate devices are identical
Intended Use /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. 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	Mimics inPrint is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. It is also used as pre-operative software for treatment planning. For this purpose, the Mimics inPrint output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Mimics inPrint should be used in conjunction with other diagnostic tools	The proposed device and primary predicate have equivalent indications.

		cardiovascular applications. Axial3D Cloud Segmentation Service should be used in conjunction with other diagnostic tools and expert clinical judgment.	and expert clinical judgment.	
Target Population		Adult	Adult	Same
Method of Use		Used in conjunction with other diagnostic tools and expert clinical judgment.	Used in conjunction with other diagnostic tools and expert clinical judgment.	The proposed device has an identical method of use to the predicate.
Imaging Modality		Computed tomograghy (CT), CT Angiography (CTA)	DICOM compliant types of imaging information	DICOM compliant types of imaging information
Environment		Hospital	Hospital	The proposed device and predicates have identical target environments
OTC or Prescription Device		Prescription Use	Prescription Use	The proposed device and predicate devices are identical
Software	**Level of Concern**	Moderate	Moderate	The proposed device and predicate devices are identical
	Verification & Validation	Complies with FDA Guidance Requirement	Complies with FDA Guidance Requirement	

Comparison of Technological Characteristics
Comparison shows the Axial3D Cloud Segmentation Service device is substantially equivalent in intended use, design, functionality, operating principles and performance characteristics of the predicate device.

Both the predicate and subject device are intended for use as a software interface and image segmentation process to facilitate the transfer of imaging information from a medical scanner to an output file. Both devices use the same segmentation functionality and generate the same output files. Both devices have functionalities to assist pre-surgical planning.

Verification and validation of both the subject and predicate devices have been performed in the same way.

It was found that minimal variances were visible between the Mesh generated from subject device and the predicate device, these variances are a result of mesh smoothing, Axial3D apply minimal smoothing to the STL file generated from the labeled images to retain a higher level of accuracy to

the original DICOM images. The validation highlighted that the subject device performed to a higher standard, than the predicate device.

The printer selection is also based on 3D printer manufacturers' guidance on the most commonly used printing technologies for the production of medical 3D printed anatomical models.

The following technological differences exist between the subject and predicate device:

- The subject device is a cloud based software platform rather than a standalone software package like the predicate

Performance Data
Non-clinical Testing

The 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.

Validation of printing of physical replica models was performed and demonstrated to be accurate when using any of the compatible 3D printers.

Conclusion

The characteristics that determine functionality and performance of the subject device, Axial3D Cloud Segmentation Service are similar to the device cleared under K173619.

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device.