Axial Medical Printing Limited
% Sujith Shetty
Executive Vice President
Maxis Medical LLC
7052 Hollow Lake Way
SAN JOSE, CALIFORNIA 95120

Re: K222745
Trade/Device Name: Axial3D Insight
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 2, 2023
Received: June 2, 2023

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 (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,

Wenbo Li for Jessica Lamb

Jessica Lamb,
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222745

Device Name
Axial3DInsight

Indications for Use *(Describe)*

Axial3DInsight 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 Axial3DInsight 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 output file or physical replica can be used for diagnostic purposes in the field of orthopedic trauma, orthopedic, maxillofacial, and cardiovascular applications.

Axial3DInsight 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.

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5 510(k) Summary

5.1 510(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: K222745

5.2 Applicant Information

Axial Medical Printing Limited

17A Ormeau Avenue

Belfast

BT2 8HD

United Kingdom

Tel: +44 (0)28 90183590

5.2.1 Contact Person

Dr. Sujith Shetty, Executive Vice President, Maxis Medical, Consultant

Email: sjshetty@maxismedical.com

Phone: 1-408-887-3211

5.3 Device Information

Trade Name	Axial3D Insight
Common Name	Automated Radiological Image Processing Software
Regulation number	892.2050
Regulation Name	Medical Image Management and Processing System
Regulatory Class	II
Product Code	QIH

5.4 Predicate Device

Table 5-1 – Predicate Device

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

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

5.5 Device Description

Axial3D Insight 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.

5.5.1 Indications for Use

Axial3D Insight 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 Insight 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 output file or the physical replica can be used for diagnostic purposes in the field of orthopedic trauma, orthopedic, maxillofacial, and cardiovascular applications.

Axial3D Insight should be used with other diagnostic tools and expert clinical judgment.

5.6 Comparison of Intended Use to Predicate and Reference Devices

Table 5-2 – Predicate Device Comparison: Intended Use

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
Device Manufacturer	Axial Medical Printing Limited	Axial Medical Printing Limited	Materialise N.V.	N/A
Device Name	Axial3D Insight	Axial3D Insight	Mimics inPrint	N/A
Device Trade or Proprietary Name	Axial3D Insight	Axial3D Insight	Mimics inPrint	N/A
510(k) Number	TBD	K221511	K173619	N/A
Device Regulation Name:	Automated Radiological Image Processing Software	Medical image management and processing system	Picture archiving and communications system	Different – Updated based on additional processing
Device Regulation Number:	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Equivalent
Device Product Code:	QIH	LLZ	LLZ	Different – Updated based on additional processing
Device Classification FDA:	Class II	Class II	Class II	Equivalent
Indication for Use	Axial3D Insight 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.	Axial3D Cloud Segmentation Service is intended for use as a cloud based service and image segmentation system for the transfer of DICOM imaging	Mimics inPrint is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
	The Axial3D Insight 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 output file or physical replica can be used for diagnostic purposes in the field of trauma, orthopedic, maxillofacial, and cardiovascular applications. Axial3D Insight should be used with other diagnostic tools and expert clinical judgment.	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.	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 can be used for diagnostic purposes in the field of orthopedic, maxillofacial, and cardiovascular applications. Mimics inPrint should be used in conjunction with	

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
			other diagnostic tools and expert clinical judgement.	
Intended Use	Axial Medical Printing Limiteds, Axial3D Insight provides patient-specific 1:1 scale replica models, either as a digital file or as a 3D printed physical model. The digital file or 3D printed physical model is intended to be used in conjunction with the DICOM images and expert clinical judgement. The applications for using the physical 3D printed physical model as a presurgical planning tool are as follows: Preoperative planning of surgical treatment options including planning for surgical instruments, aiding decisions on implants, and aiding the surgical treatment plan., All planning using the 3D replica model should be carried out	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	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	Similar

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
	with the assistance of the DICOM images Communication with the surgical team to discuss the surgical treatment plan in conjunction with DICOM images Communication with the patient to discuss the surgical treatment plan in conjunction with DICOM images Education tool for surgical planning. The 3D printed physical model can be used for surgical planning in the following applications: orthopedics and trauma, maxillofacial, and cardiovascular surgery.	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.	cardiovascular applications. Mimics inPrint should be used in conjunction with other diagnostic tools and expert clinical judgement.	
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.	Used in conjunction with other diagnostic tools and expert clinical judgement.	Equivalent
Environment	Hospital	Hospital	Hospital	Equivalent
OTC or Prescription Device	Prescription Use	Prescription Use	Prescription Use	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
Level of Concern	Moderate	Moderate	Moderate	Equivalent
V&V	Complies with FDA Guidance Requirement	Complies with FDA Guidance Requirement	Complies with FDA Guidance Requirement	Equivalent

5.7 Comparison of Technological Characteristics to the Predicate Device and Reference Device

Table 5-3 – Predicate Comparison: Technology

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
Method of Use	software interface	software interface	software interface	Equivalent
Computer Platform and Operating System	Microsoft Edge (v104), Safari (v15) or Chrome (v103) or equivalent	Internet Explorer 11 or equivalent	Windows 7 – 64bit Internet Explorer 8 and compatible Intel Core 2 Duo / AMD X2 AM2 or equivalent	The proposed device only requires Microsoft Edge (v104), Safari (v15) or Chrome (v103) or equivalent to operate. Underlying hardware is irrelevant to the user as it is hosted by Axial Medical. The change does not affect establishing

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
				substantial equivalence as the output of the proposed device and predicate devices is equivalent.
Supported Modalities	CT and CTA	CT	CT, MRI, X-ray	The proposed device uses a subset of the predicate device image modalities
Image registration	Yes	Yes	Yes	Equivalent
Segmentation Features	A combination of automated tools with smart editing tools	A combination of automated tools with smart editing tools	Combination of automated tools with smart editing tools	Equivalent
View Manipulation and Volume Rendering	Yes	Yes	Yes	Equivalent
Regions and Volumes of Interest (ROI)	Orthopedics / Trauma Cardiovascular Cranio-Maxillofacial	Orthopedics / Trauma Cardiovascular Cranio-Maxillofacial	Orthopedics / Trauma Cardiovascular Cranio-Maxillofacial	Equivalent
Region/volume of interest measurements and size measurements	Yes	Yes	Yes	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Cloud Segmentation Service (Predicate Device)	Mimics InPrint (Reference Device)	Comparison
Region/Volume Quantification	Yes	Yes	Yes	Equivalent

5.8 Performance Data

5.8.1 Axial3D Insight Device Validation

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.

In addition to the human factors validation of the Axial3D Insight device, Axial3D conducted two validation studies - the Clinical Segmentation performance and the Intended Use of the device output - the 3D patient specific model.

The Clinical Segmentation Performance study was conducted with 3 radiologists reviewing the segmentation of 12 cases across the fields of orthopedics, trauma, maxillofacial and cardiovascular. Axial3D adopted a peer reviewed medical imaging review framework of RADPEER to capture the assessment and feedback from the radiologists involved - all cases were scored within the acceptance criteria of 1 or 2a [1].

The Intended Use validation study of the device was conducted with 9 physicians reviewing 12 cases across the fields of Orthopedics, Trauma, Maxillofacial, and Cardiovascular, as defined in the Intended Use statement of the device. This study concluded successful validation of the 3D models produced by Axial3D demonstrating the device outputs satisfied end user needs and indications for use.

5.8.2 Axial^{ML} Machine Learning Validation

Axial^{ML} machine learning models are used to generate an initial segmentation of cases, however the output of these models is not used in isolation to produce the final 3D patient specific model. The segmentations produced by the Axial^{ML} machine learning models are used by Axial3D trained

staff who complete the final segmentation and validation of the quality of each 3D patient specific model produced.

Axial^{ML} machine learning models were independently verified and validated before inclusion in the Axial3D Insight device. Details of the data used in the validation of each machine learning model is provided below.

Table 5-4 – Software Validation Data

	Cardiac CT/CTa	Neuro CT/CTa*	Ortho CT	Trauma CT
Number of Images Used for Validation	4,838	4,041	10,857	19,134
Slice Spacing Range (Min, Max [mm])	0.4 - 0.8	0.44 - 1.0	0.3 - 2.0	0.2 - 2.0
Slice Spacing Average [mm]	0.54	0.63	0.79	0.76
Pixel Size Range (Min, Max [mm])	0.23 - 0.78	0.34 - 0.70	0.18 - 0.98	0.22 - 0.98
Pixel Size Average [mm]	0.46	0.51	0.44	0. 51

*NeuroCT/CTa model is used for cardiology cases.

The imaging scanner manufacturers and models used within the validation dataset are listed below.

Table 5-5 – Imaging scanner manufacturers and models used for the validation datasets

Manufacturer	Model
GE Medical Systems	Lightspeed Pro 16 Lightspeed Pro 32 Revolution CT Optima CT660 Discovery CT750 HD
Siemens	SOMATOM Definition Flash SOMATOM Definition Edge SOMATOM Definition AS SOMATOM Definition AS+ SOMATOM Perspective

Manufacturer	Model
	SOMATOM Force Sensation 16 AXIOM-Artis Emotion 16
Phillips	IQON Spectral CT iCT 128 iCT 256 Ingenuity Core 128 Brilliance 62
Toshiba	Aquillon PRIME Aquillon PRIME SP

The Axial^{ML} machine learning model training data used during the algorithm development was explicitly kept separate and independent from the validation data used.

5.9 Conclusions:

Based on the indications for use, product performance, and clinical information provided in this notification, the Axial3D Insight is considered substantially equivalent to the marketed predicate device, Axial3D Cloud Segmentation Service. Both the predicate device and the Axial3D Insight have similar DICOM segmentation and 3D model creation. This 510(k) notification contains the technological characteristics and validation and verification to demonstrate the Axial3D Insight does not raise any different questions regarding safety and effectiveness compared to the predicate, Axial3D Cloud Segmentation Service.