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

Re: K232841
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: October 19, 2023
Received: October 20, 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 (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, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: 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)*
K232841

Device Name
Axial3D Insight

Indications for Use *(Describe)*

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 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.

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

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: K232841

5.1 Applicant Information

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

5.1.1 Contact Person

Joanne Flatley, QA/RA Lead

5.2 Device Information

Trade Name	Axial3D Insight
Common Name	Automated Radiological Image Processing Software
Classification number:	892.2050
Regulatory Class	II
Product Code	QIH

5.3 Predicate Device

Table 5-1 - Predicate Device

Name	Manufacturer	510(k)#
Axial3D Insight	Axial Medical Printing Limited	K222745

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

5.4 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.

5.4.1 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 trauma, orthopedic, maxillofacial, and cardiovascular applications.

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

5.5 Comparison of Intended Use to Predicate and Reference Devices

Table 5-2 – Predicate Device Comparison: Intended Use

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
Device Manufacturer	Axial Medical Printing Limited	Axial Medical Printing Limited	N/A
Device Name	Axial3D Insight	Axial3D Insight	N/A
Device Trade or Proprietary Name	Axial3D Insight	Axial3D Insight	N/A
510(k) Number	K232841	K222745	N/A
Device Regulation Name:	Automated Radiological Image Processing Software	Automated Radiological image Processing Software	Equivalent
Device Regulation Number:	21 CFR 892.2050	21 CFR 892.2050	Equivalent
Device Product Code:	QIH	QIH	Equivalent
Device Classification FDA:	Class II	Class II	Equivalent
Indication for Use	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.	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.	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
	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.	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.	
Intended Use	Axial Medical Printing Limited's, 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 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	Axial Medical Printing Limited's, 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 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	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
	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.	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.	
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
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

5.6 Comparison of Technological Characteristics to the Predicate Device

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
Method of Use	software interface	software interface	Equivalent
Computer Platform and Operating System	Microsoft Edge (v104), Safari (v15) or Chrome (v103) or equivalent	Microsoft Edge (v104), Safari (v15) or Chrome (v103) or equivalent	Equivalent
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	Yes	Yes	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
Volume Rendering			
Regions and Volumes of Interest (ROI)	Orthopedics / Trauma Cardiovascular Cranio- Maxillofacial	Orthopedics / Trauma Cardiovascular Cranio- Maxillofacial	Equivalent
Region/volume of interest measurements and size measurements	Yes	Yes	Equivalent
Region/Volume Quantification	Yes	Yes	Equivalent
Approved Printers	**Formlabs** • Form 3B **Stratasys** • J750 • J5 Medijet • J850 • Origin One **HP** • HP580 • HP540	**Formlabs** • Form 3B **Stratasys** • J750 • J5 Medijet **HP** • HP580 • HP540	Similar
Approved Materials	**Formlabs** • Form 3B ○ Standard White V4 FLGPWH04 ○ Standard Draft V2 FLDRGR02 ○ Standard Clear V4 FLGPCL04 ○ Flexible 80A V1 FLFL8001 **Stratasys** • J750 ○ Agilus, ○ VeroBlackPlus, ○ VeroClear,	**Formlabs** • Form 3B ○ Standard White V4 FLGPWH04 ○ Standard Draft V2 FLDRGR02 ○ Standard Clear V4 FLGPCL04 ○ Flexible 80A V1 FLFL8001 **Stratasys** • J750 ○ Agilus, ○ VeroBlackPlus, ○ VeroClear,	Similar

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
	○ VeroCyan, ○ VeroGrey, ○ VeroMagenta, ○ VeroPureWhite, ○ VeroYellow • J5 Medijet ○ VeroVividTMCyan, ○ VeroVividTMMagenta, ○ VeroVividTMYellow, ○ DraftWhite, ○ MED610, ○ MED615RGD, ○ VeroUltraClearTM ○ ElasticoTMClear • J850 ○ VeroVividTMCyan, ○ VeroVividTMMagenta, ○ VeroVividTMYellow, ○ VeroPureWhite ○ BoneMatrixTM ○ GelMatrixTM ○ TissueMatrixTM ○ RadioMatrixTM ○ Agilus30 ○ VeroClear ○ VeroMagenta ○ BlackPlus • Origin One ○ ORIGIN DM100 by BASF ○ ORIGIN DM200 by BASF ○ LOCTITE 3D 3843 ○ LOCTITE 3D IND405 **HP** • HP580 ○ Nylon PA12 • HP540	○ VeroCyan, ○ VeroGrey, ○ VeroMagenta, ○ VeroPureWhite, ○ VeroYellow • J5 Medijet ○ VeroVividTMCyan, ○ VeroVividTMMagenta, ○ VeroVividTMYellow, ○ DraftWhite, ○ MED610, ○ MED615RGD, ○ VeroUltraClearTM ○ ElasticoTMClear **HP** • HP580 ○ Nylon PA12 • HP540 ○ Nylon PA12	

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device K222745)	Comparison
	○ Nylon PA12		

5.7 Performance Data

5.7.1 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, per FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued in 2005. The update to the product that is the subject of this premarket notification does not affect the current software validation, as only new materials and printers are being added to the product. Axial3D is aware that the FDA software guidance was updated in 2023, but since the software portion of the Axial insight product is not being updated as a part of this submission, testing in accordance with the previous guidance remains applicable.

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:

- Clinical Segmentation Performance Study
- Intended Use Validation Study

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.

** "ACR RADPEER committee white paper with 2016 updates: revised scoring system, new classifications, self-review, and subspecialized reports." Journal of the American College of Radiology 14.8 (2017): 1080-1086.*

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.

5.7.2 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 5-3: 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 in mm)	0.4 - 0.8	0.44 - 1.0	0.3 - 2.0	0.2 - 2.0
Slice Spacing Average (in mm)	0.54	0.63	0.79	0.76
Pixel Size Range (Min, Max in 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 variety of image scanner manufacturers and models used within the validation dataset are listed below.

Table 5-4 – Imaging scanner manufactures 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 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.

5.7.3 Phantom Testing

5.7.3.1 Verification of the Stratasys Origin One Printer and materials

The verification testing of the Origin One printer involved printing 3D test phantoms provided by the National Institute of Standards and technology (NIST). This object provides a realistic challenge to the geometry the printer will need to replicate to print anatomical models. Similar features are present in anatomical structures such as thin walls, flat surfaces, holes, and overhangs. The NIST test phantom also makes possible a detailed evaluation of a range of small, medium, and large features, which also replicate anatomical features while allowing repeated measurements to determine accuracy and repeatability as outlined in Slide 12 FDA/CDRH–RSNA SIG Joint Meeting on 3D Printed Patient-Specific Anatomic Models.

This verification test establishes that the printer can reproduce the required geometry to an acceptance criterion of ± 0.3mm, the same acceptance criteria used to verify the predicate device (Axial 3D Insight, **K222745**)

5.7.3.2 Verification of the Stratasys J850 and materials

Axial Medical Printing verified the Stratasys J850 printer as part of the design control process. Testing was performed on the J850 by Stratasys, who provided a test report detailing the verification activity.

Verification testing for the J850 printer is appropriate to establish that the Axial3D Insight device can produce anatomical models with the required accuracy of the product, as established in **K222745**

5.8 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 Insight (K222745). 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 Insight (K222745).