



Axial Medical Printing Limited
% May Lee
Senior Consultant
CS Lifesciences Ltd
Suite 10, Dunswood House
1 Dunswood Road, Cumbernauld
Glasgow, G67 3EN
United Kingdom

September 18, 2025

Re: K250369

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: August 19, 2025
Received: August 19, 2025

Dear May Lee:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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
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

Indications for Use

Submission Number (if known)

K250369

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

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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 CFR 807.92.

Date Prepared: September 17, 2025

2. Applicant Information

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United Kingdom
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3. Contact Person

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1 Dunnswood Road,
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United Kingdom
Email: may@cslifesciences.com

4. Device Information

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

5. Predicate Device

Table 5 - Predicate Device

Name	Manufacturer	510(k)#
Axial3D Insight	Axial Medical Printing Limited	K232841

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

6. 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.

a. 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.

7. Comparison of Intended Use to Predicate and Reference Devices

Table 2 – Predicate Device Comparison: Intended Use

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device)	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	K250369	K232841	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

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device)	Comparison
Device Classification FDA	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. The Axial3D Insight output file can be used for 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 in conjunction with other diagnostic tools and expert clinical judgement.	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 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 in conjunction with other diagnostic tools and expert clinical judgement.	Equivalent
Intended Use	Axial Medical Printing Limited, 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 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	Axial Medical Printing Limited, 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 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	Equivalent

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (Predicate Device)	Comparison
	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, trauma, maxillofacial, and cardiac surgery.	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, trauma, maxillofacial, and cardiac surgery.	
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.	Equivalent
Use Environment	Hospital	Hospital	Equivalent
OTC or Prescription Device	Prescription Use	Prescription Use	Equivalent
V&V	Complies with FDA Guidance Requirement	Complies with FDA Guidance Requirement	Equivalent
PCCP	Will have access to approved PCCP	Will have access to approved PCCP	Different – the premise of this 510k is to have the PCCP approved

8. Comparison of Technological Characteristics to the Predicate Device and Reference Device

Table 3 Predicate Comparison: Technology

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

Attribute	Axial3D Insight (Proposed Device)	Axial3D Insight (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)	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

9. Performance Data

a. Axial3D Insight Device Validation

Axial3D performed software design verification and validation testing on all three software components of the device. 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.

* "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.

b. 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 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 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.

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 AxialML machine learning model training data used during the algorithm development was explicitly kept separate and independent from the validation data used.

10. Predetermined Change Control Plan (PCCP)

Axial3D Insight contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, enacted on December 29, 2022. Modifications to the AxialML models of Axial3D Insight will be made in accordance with its Predetermined Change Control Plan (PCCP). The PCCP provides a description of the device's planned modifications, a modification protocol to test, verify, validate, and implement the modifications in a manner that ensures the continued safety and effectiveness of the device. This protocol also includes control measures that mitigate risks associated with changes to the AxialML model components, including an impact assessment of the planned modifications, to ensure modifications conducted in line with the modification protocol will not adversely impact the device's performance, safety, or effectiveness associated with its indications for use. The modifications outlined in the PCCP are summarized in the table below. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field.

Axial3D Insight is a cloud hosted platform, therefore, any software updates resulting from a modification implemented in line with the authorised PCCP will require no action from the end user. Any impact of the

implemented modification on the device's performance, inputs or use will be detailed in an updated IFU, which will be made available on the company website in conjunction with the release of a software update with the implemented modification. This information shall be made available to the user so that they may understand the changes, if applicable, to the device and continue to use the device safely and effectively across the relevant intended use populations and within the indications for use. The PCCP specifies a list of potential modifications to the device software as well as specific verification and validation activities in place to implement these modifications in a controlled manner such that the modified device remains safe and effective.

Table 5: Potential Modifications List

ID	Summary	Trigger for Retrain	Timeframe
MOD_ML_001	Increasing Volume of Training, Tuning and Testing data	Newly available or identified source(s) of data representing the original intended use population	Reviewed periodically every 6 months
MOD_ML_002	Semantic Sub-Labeling	Internal R&D activities demonstrating benefits from introducing semantic sub-labelling that increase the effectiveness of Axial ^{ML} output as utilized by Axial3D internal engineers	Within 18 months
MOD_ML_003	Introduction of New Assistive Labeling	Internal R&D activities demonstrating performance benefits from introducing assistive labels that increases the effectiveness of Axial ^{ML} output as utilized by Axial3D internal engineers	Reviewed periodically every 6 months
MOD_ML_004	Model Parameter and Hyperparameter Tuning	Internal R&D activities demonstrating performance benefits from parameter and hyperparameter tuning that increases the effectiveness of Axial ^{ML} output as utilized by Axial3D internal engineers	Reviewed periodically every 12 months
MOD_ML_005	Performance Increasing Library Updates	Newly available library or dependency updates, of component utilized in the original device that increases the effectiveness of Axial ^{ML} output as utilized by Axial3D internal engineers	Reviewed periodically every 6 months

11. PCCP Performance Verification & Validation

These activities focus on the specific performance and safety of the modified AxialML machine learning models themselves, independent of their integration into the broader system. The purpose of these activities is to verify and validate that the modified ML model meets its design inputs and acceptance criteria before being considered for integration into the Axial3D Insight device.

a. Verification Activities:

Peer Code Review: Ensures the quality and correctness of the underlying code for the AxialML models.

Unit Testing: Verifies individual components or units of the AxialML code function as intended.

Quantitative 3D Medical Image Segmentation Metric Analysis: This is a crucial step where the performance of the modified ML model is quantitatively assessed using a broad range of independent test datasets that are representative of the intended use population. We utilize a suite of metrics including Dice Coefficient, Pixel Accuracy, Area Under the Curve (AUC), Precision, and Recall to provide a robust indicator of segmentation performance, comparing the candidate modified AxialML model against the model version from the original submission. These metrics are calculated for each individual label and/or as an averaged performance. The performance must demonstrate equivalence or improvement to be considered for the next phase, Validation. This activity serves as a core component of our internal model development and verification, ensuring that any model modifications conducted in line with the modification protocol must consistently meet performance standards before further integration and validation.

b. Validation Activities:

Qualitative Assessment using Independent Test Datasets: Once quantitative metrics show promise, candidate models undergo a qualitative assessment. This involves a pool, minimum of 3, of Axial3D Medical Visualization Engineers reviewing the segmentations generated by the modified AxialML model, against segmentations generated from the unmodified model, for a consistent set of independent test datasets from the original submission. This assessment utilizes a fixed evaluation methodology to define improved, equivalent or reduced performance based on the AxialML Model Design Input Specifications. This activity confirms validation by producing objective evidence, that demonstrates each AxialML Model Design Input Specification has been met and the model output supports Axial Staff in completing anatomical segmentation for patient-specific 3D models, in line with the device intended use.

Quantitative Assessment using Expert Reference Standard: The validation activities also include the use of a fixed number of expert reference standards, independently sourced datasets commissioned from US

only sites, representative of the intended use population and independently segmented and reviewed by expert radiologists. These expert reference standards remain unchanged from the original submission and shall be used as a consistent baseline to determine any potential modification has not adversely affected the device performance, as determined by comparing the original model baseline vs modified model performance using a combination of quantitative metrics including DICE, AUC, Precision, Accuracy and Recall. The mean of the identified quantitative metrics must demonstrate equivalence or an improvement for the proposed modified AxialML model to be successfully validated in line with the modification protocol.

Hazard Analysis Review: As part of the Verification & Validation activities, the device hazard analysis is reviewed to identify and address any potential biases and limitations introduced by the model modifications, ensuring that any relevant risk control measures, new or modified, are captured and verified.

12. Conclusion:

A review of the indication for use, operating environment, device class, method of use, software level of concern, technical characteristics, and technical specifications indicate the Axial3D Insight is substantially equivalent to the FDA cleared and marketed device, Axial3D Insight (K232841). Both devices are to be used as an image segmentation tool to create 3D replicas from 2D medical images. The addition of a PCCP is the only difference between the proposed device and the predicate and reference devices. The differences between the proposed device and the predicate device do not raise any new concerns of safety or efficacy.