March 24, 2026

Shimadzu Corporation
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

Re: K252099
Trade/Device Name: Trinias
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, QIH
Dated: February 10, 2026
Received: February 10, 2026

Dear Daniel Kamm:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252099 |

Please provide the device trade name(s).

Trinias

Please provide your Indications for Use below.

The Trinias is an angiographic X-ray system which is used for diagnostic imaging and interventional procedures. The Trinias is intended to be used for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational angiography, multi-purpose angiography and whole body radiographic/fluoroscopic procedures

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252099

# 510(k) Summary

Prepared on: 2026-03-23

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Shimadzu Corporation |
| Applicant Address | 1, Nishinokyo Kuwabara-cho, Nakagyo-ku, Kyoto 604-8511 Japan |
| Applicant Contact Telephone | +81-75-8231305 |
| Applicant Contact | Mr. Koichi Kataoka |
| Applicant Contact Email | k_koichi@shimadzu.co.jp |
| Correspondent Name | Kamm & Associates |
| Correspondent Address | 8870 Ravello Ct Naples FL 34114 United States |
| Correspondent Contact Telephone | 847-374-1727 |
| Correspondent Contact | Mr. Daniel Kamm, P.E. |
| Correspondent Contact Email | fda.help.now@gmail.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Trinias |
| Common Name | Interventional Fluoroscopic X-Ray System |
| Classification Name | Image-intensified fluoroscopic x-ray system |
| Regulation Number | 892.1650 |
| Product Code(s) | OWB, QIH |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K221922 | Trinias | OWB |

## Device Description Summary

21 CFR 807.92(a)(4)

Trinias is an interventional fluoroscopic x-ray system which uses digital x-ray receptor panels for image acquisition. The system has been modified to include new image enhancement software feature called "SCORE Opera," This new feature applies AI (deep learning technology) filter technology to enable efficient noise suppression and contrast enhancement, and to improve the visibility of devices that are generally difficult to achieve under low dose conditions, catheters for example.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Trinias is an angiographic X-ray system which is used for diagnostic imaging and interventional procedures. The Trinias is intended to be used for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational angiography, multi-purpose angiography and whole body radiographic/fluoroscopic procedures

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same as the predicate. The modified device provides improved image processing. The enhancement is called SCORE Opera. SCORE Opera applies AI (deep learning technology) filter technology to enable efficient noise suppression and contrast enhancement, and to improve the visibility of devices that is generally difficult to achieve under low dose conditions. In addition to reducing radiation exposure, the burden of image diagnosis to physicians will be reduced, reducing treatment time. The system indications for use remains unchanged: The Trinias is an angiographic X-ray system which is used for diagnostic imaging and interventional procedures. The Trinias is intended to be used for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational angiography, multi-purpose angiography and whole body radiographic/fluoroscopic procedures

## Technological Comparison

21 CFR 807.92(a)(6)

Both the predicate and the proposed devices have the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc but the modified device provides improved image enhancement capabilities.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The software was developed and tested in accordance with these FDA Guidance Documents: Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff AND Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff. The software was then subjected to non-clinical testing. Summary of non-clinical testing: We provided these detailed non-clinical test reports: The SCORE Opera Development process of leaning model AND a 2D Image Quality Evaluation Report.

Clinical testing: A clinical image quality study was conducted. The objective of the study was to evaluate the clinical image quality of X-ray images processed by the Trinias system's AI algorithm. The study aims to confirm that the AI-enhanced images (AI-ON) maintain diagnostic quality compared to standard processing (AI-OFF). This assessment is submitted to support the determination of substantial equivalence. The results confirm that the AI-ON processing frequently provides improved visibility of interventional devices and vessels.

After reviewing all of the nonclinical tests we conducted on our modified device, we have concluded that our device is as safe and effective as our predicate device and it does not present any new issues of safety and effectiveness. Our modified device performs as well as or better than our predicate. Clinical testing is not required for a finding of substantial equivalence.