July 28, 2022

Shimadzu Corporation Medical Systems Division
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K221922
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
Dated: June 30, 2022
Received: July 1, 2022

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 (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,

Laurel Burk, 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

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)*
K221922

Device Name
Trinias

Indications for Use *(Describe)*

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

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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510(k) Summary: 510(k) Number K221922

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Registration Number: 8030233
Phone: +81-75-823-1305 Fax: +81-75-823-1377
Date Prepared: July 26, 2022
Contact: Koichi Kataoka, General Manager, Quality Assurance Department, Medical Systems Division

1. **Identification of the Device:**
   Trade/Device Names: Trinias
   Regulation Number: 21CFR892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB
   Common/Usual Name: Interventional Fluoroscopic X-Ray System

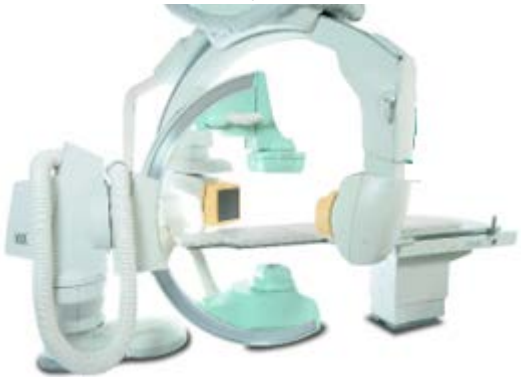
2. **Equivalent legally marketed device: K203535**
   Trade/Device Name: Trinias
   Manufacturer: Shimadzu.
   Regulation Number: 21CFR892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB
   Common/Usual Name: Interventional Fluoroscopic X-Ray System

3. **Indications for Use: 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**.

4. **Description of the Device:** This notification is for a modified device. The modification is the addition of the new MH-700 (ceiling mounted C-Arm). This is the functional equivalent of previous C-Arm MH-400. All options declared under K203535 remain available. The Lateral Angiographic C-arm Support MH-700 allows examination of a patient by fluoroscopy or radiography from different angles with the patient kept in a horizontal position in combination with a Frontal C-arm Support MH-600, an X-ray high voltage unit, X-ray tube unit, X-ray image recording unit (FPD), digital angiography system, catheterization table, etc. The range of available digital receptor panels remains unchanged from our predicate K203535. For installation, ceiling strength is important because the total weight of MH-700 exceeds 1200 kg. The MH-700 features faster movement speeds as compared to the previous model, the MH-400**.**

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and standards testing indicates that the modified device is as safe and effective as the predicate device. Proper system operation is fully verified upon installation. Most of the components employed are identical to the predicate device**.**

6. Substantial Equivalence Chart: Below.

	Trinias K203535	Modified Trinias
Indications for Use:	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.	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 statement has not changed.
Patient Table	KS-100, table top can tilt.	Same as predicate
	Bi-plane C-Arms	
Biplane C-arm (Combines a floor mounted C-arm with a ceiling mounted C-arm)	MH-300 plus MH-400	MH-600 plus MH-700 (MH-700 is new) (MH-600 previously cleared)
Picture of equivalent assembly	MH-300/MH-400 	MH-600/MH-700 
Comparison of Equivalent Assemblies: MH-400 vs MH-700		
Lateral C-arm	MH-400 (K123508)	MH-700
Mounting	Ceiling	Same
Variation of position	LL position / RL Position	Same
LL position Primary angle) C-arm rotation range and Speed	"LAO120 - PA0 Max 15deg/sec" (LAO=Left Anterior Oblique) (PA= Postero-Anterior projection)	"LAO120 - PA0 Max 25deg/sec" Faster response
RL position Primary angle) C-arm rotation range and Speed	"PA0 - RAO120 Max 15deg/sec" (RAO= Right Anterior Oblique)	"PA0 - RAO120 Max 25deg/sec" Faster response

	Trinias K203535	Modified Trinias
LL position Secondary Angle C-arm rotation range and Speed	"CRAN45 - CAUD45 Max 15deg/sec" (CRAN=Caudo-Cranial projection) (CAUD=Cranio-Caudal projection)	"CRAN45 - CAUD45 Max 25deg/sec" Faster response
RL position Secondary Angle C-arm rotation range and Speed	"CRAN30°～CAUD30° Max 15deg/sec"	"CRAN45 - CAUD45 Max 25deg/sec" Faster response
SID range/speed	95cm - 125cm , 8cm/sec max	95cm - 125cm, 10cm/sec max Faster response
Digital Image Processor	DAR-9500f	Same as predicate
Digital X-Ray Receptor Panels (No changes) Shimadzu Reference/Manufacturer Model		
SIZE: 8" x 8"	SFD-0808AF Varex PaxScan 2020X (194µm)	Same as predicate
SIZE: 12" x 12"	SFD-1212AF Varex PaxScan 3030X (194µm	Same as predicate
SIZE: 16" x 12"	SFD-1612AF Varex PaxScan 4030X (194µm)	Same as predicate
X-Ray Generation		
Generator	100 kW	Same as predicate
Model #	D150GC-40	Same as predicate
Control Method	50 kHz Inverter	Same as predicate
Rated output	100 kW	Same as predicate
Radiography tube Voltage	40 kV- 150 kV	Same as predicate
Radiography tube current	10 to 1250 mA	Same as predicate
Radiography mAs	0.5 to 800 mAs	Same as predicate
Radiography time	0.001 to 10 sec	Same as predicate
Fluoroscopy tube voltage	50 kV to 125 kV	Same as predicate
Fluoroscopy tube current	0.3 to 38 mA	Same as predicate
Short time rating	100 kV – 1000 mA	Same as predicate
Long time rating	100 kV - 38mA	Same as predicate
Collimator	F-100: Has 16 BH filters with irridation area of 421 x 421 mm max. New collimator offers more filtration options.	Same as predicate
US Performance Standard	21CFR1020.30, 21CFR1020.31 and 21CFR2020.32	Same as predicate
IEC Safety Standards	See list below	Same as predicate

7. **Summary of non-clinical testing:** Software was validated according to the FDA Guidance: Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014*. The digital panel software employed was already reviewed by FDA. Labeling was developed and information provided in accordance with this FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff, November 2017.* Labeling also includes reference to the Image Gently website (http://www.imagegently.org/). Because the device contains wireless technology, we consulted *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff, AUGUST 2013* and we incorporated those recommendations into our labeling**.**

   This device has been tested and is certified to comply with the US Radiation Safety Performance Standards as listed in the table above. Performance and safety testing was conducted by third party NRTL certified testing laboratories and the device was found to comply with the following FDA recognized standards:

   - US Performance Standard: 21CFR1020.30, 21CFR1020.31 and 21CFR2020.32
   - IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA 19-4
   - IEC 60601-1-2:2014 Collateral Standard: Electromagnetic disturbances - Requirements and tests FDA 19-8
   - IEC 60601-1-3:2008 + A1:2013 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment FDA 12-269
   - IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA 5-89
   - IEC 60601-2-43:2010 +A1:2017 +A2:2019 Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures FDA 12-329
   - Additionally evaluated in accordance with
   - IEC 62366: 2007 + A1: 2014 Medical devices - Part 1: Application of usability engineering to medical devices FDA 5-114
   - IEC 62304: 2006 Medical device software - Software life cycle processes FDA 13-79
   - EN 60601-1:2006 + A11:2011 + A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   - EN 60601-1-3:2008 + A1:2013 + A11:2016 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
   - EN 60601-1-6:2010 + A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
   - EN 60601-2-43:2010 + A1:2018 Medical electrical equipment - Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
   - EN 62304:2006 Medical device software - Software life cycle processes
   - ANSI/AAMI ES60601-1:2005 + A2:2010 + A1:2012

We consulted the following FDA guidance documents in the development of the Trinias: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff;* and *Pediatric Information for X-ray Imaging Device Premarket Notifications.*

8. **Summary of clinical testing:** Not applicable. Clinical testing was not deemed to be required to show substantial equivalence. We relied on non-clinical testing and compliance with standards**.**

9. **Conclusion:** After analyzing standards compliance results and bench tests, it is the conclusion of Shimadzu Corporation that the MODIFIED Trinias is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.