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

April 28, 2021

Re: K203535
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: March 29, 2021
Received: March 30, 2021

Dear Mr. 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,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203535

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: 510(k) Number K203535

Shimadzu Corporation
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto, 604-8511, Japan
Registration Number: 8030233
Phone: +81-75-823-1305 Fax : +81-75-823-1377
Date Prepared: March 29, 2021
Contact: Shigeru Naganishi; Phone: +81-75-823-1920
E-mail: shige@shimadzu.co.jpshige@shimadzu.co.jp

1. **Identification of the Device:**
   Trade/Device Names: Trinias
   Regulation Number: 21 CFR 892.1650
   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: K123508**
   Trade/Device Name: Trinias
   Manufacturer: Shimadzu.
   Regulation Number: 21CFR892.1650
   Regulation Name: Interventional Fluoroscopic X-Ray System
   Regulatory Class: II
   Product Code: OWB
   Common/Usual Name: Interventional Fluoroscopic X-Ray System

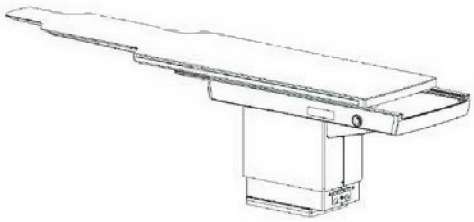
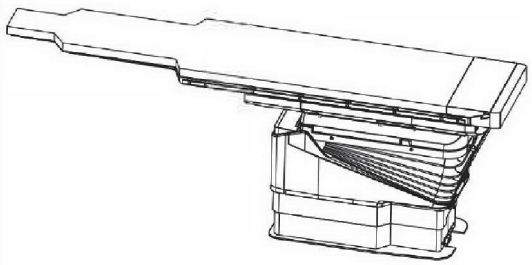
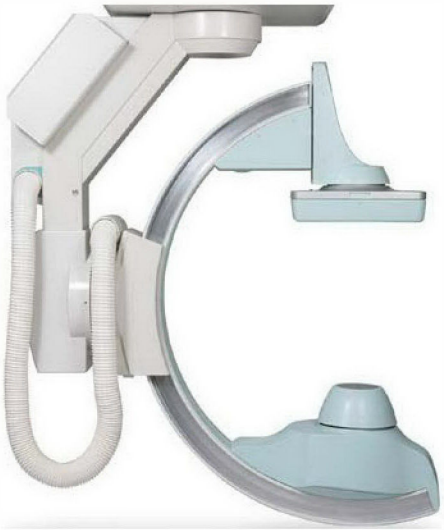
3. **Indications for Use (intended use):** The Trinias is an angiographic X-ray system, which is used for diagnostic imaging and interventional procedures. The Trinias is intended to be used for cardiac angiography, neurovascular angiography, abdominal angiography, peripheral angiography, rotational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

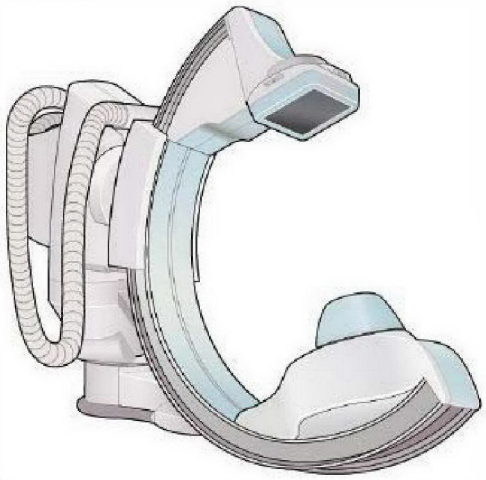
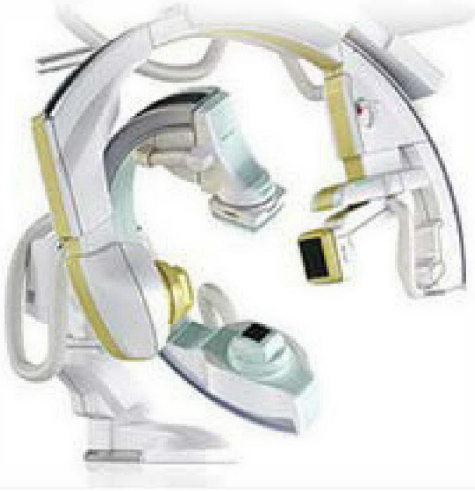
4. **Description of the Device:**
   This notification is for a modified device. The modifications are:
   Updated user interfaces (wireless mouse, keyboard)
   A new model of catheterization table
   A new type of digital system console
   Additional x-ray tube choices
   Add alternate choices for the same sizes of digital flat panel detectors
   An additional size of available flat panel detector (12" x 16")
   An additional type of control cabinet.
   Model identifications:
   KS-70 Patient Table
   KS-100 New Patient Table
   F-100 New Collimator
   LX-6308, LX-6311, E79039X: X-ray Tubes
   DAR-9500f, Digital Angiography System; Flat panel.
   New MH-500 Suspended C-Arm

New MH-600 Lateral C-Arm
D150GC-40 High Voltage Generator

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and standards testing indicates that the new 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 K123508	**Modified Trinias**
Indications for Use:	The Trinias is an angiographic X-ray system, which is used for diagnostic imaging and interventional procedures as described in 21 CFR 892.1650. 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. (SAME except CFR reference removed for international consistency)
Patient Table	KS-70 	Newly available: KS-100, table top can tilt. 
C-arms		
Ceiling	MH-200S 	MH-500 

	Trinias K123508	Modified Trinias
Floor	MH-300  MH-300/400 Biplane 	MH-600  MH-300/400 Biplane is still available under K123508.

Digital X-Ray Receptor Panels Comparison		
SIZE:	Shimadzu Reference/ Manufacturer Model	Shimadzu Reference/ Manufacturer Model
9" x 9"	PANEL MAIN ASSY, A-9	(No longer available)
17" x 17"	PANEL MAIN ASSY, S-17	(No longer available)
8" x 8"	SFD-0808 Varex PaxScan 2020+ (194µm)	SFD-0808AF Varex PaxScan 2020X (194µm) (Updated version of the predicate)
12" x 12"	SFD-1212 Varex PaxScan 3030+ 194µm	SFD-1212AF Varex PaxScan 3030X (194µm) (Updated version of the predicate)
16" x 12"	This size was not available	SFD-1612AF Varex PaxScan 4030X (194µm) (Updated version of the predicate)
X-Ray Generation		

	Trinias K123508	Modified Trinias
Generator	100 kW	SAME
Model #	D150GC-40	Same as predicate
Control Method	50kHz Inverter	Same as predicate
Rated output	100kW	Same as predicate
Radiography tube Voltage	40kV - 150kV	Same as predicate
Radiography tube current	10 to 1250mA	Same as predicate
Radiography mAs	0.5 to 800mAs	Same as predicate
Radiography time	0.001 to 10sec	Same as predicate
Fluoroscopy tube voltage	50kV to 125kV	Same as predicate
Fluoroscopy tube current	0.3 to 30mA	0.3 to 38mA
Short time rating	100kv - 1000mA	Same as predicate
Long time rating	100kv - 30mA	100kV - 38mA
Collimator	F-50: Has 4 BH (beam hardening) filters with Irradiation area of 400 x 400 mm max	F-100: Has 16 BH filters with irridation area of 421 x 421 mm max. New collimator offers more filtration options.
Safety Standards		
US Performance Standard	21CFR1020.30, 21CFR1020.31 and 21CFR2020.32	SAME
IEC Safety Standards	See list below	SAME

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 Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures FDA 12-308
- 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 - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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.