June 26, 2024

Dornier MedTech America
℅ John Hoffer
VP Quality/Regulatory
1155 Roberts Blvd
KENNESAW, GA 30144

Re: K233380
Trade/Device Name: Trident Mobile Fluoroscopy System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA
Dated: May 24, 2024
Received: May 24, 2024

Dear John Hoffer:

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,

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

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)*

K233380

Device Name

Trident Mobile Fluoroscopy System

Indications for Use *(Describe)*

The Trident Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

Type of Use *(Select one or both, as applicable)*

X 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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K233380

510(k) SUMMARY

Dornier's Trident Mobile Fluoroscopy System

Submitter
Dornier MedTech America 1155
Roberts Blvd.
Kennesaw, GA 30144
Date Prepared: June 25, 2024
Contact Person: John Hoffer
Phone: 770-514-6163

Name of Device: Trident Mobile Fluoroscopy System
Common or Usual Name: Image Intensified Fluoroscopic X-ray System
Classification Name: Image Intensified Fluoroscopic X-ray System
Regulatory Class/ Regulation Number: Class II / 21 C.F.R. § 892.1650
Product Code: JAA

Predicate Device OEC 9900 Elite (K120613)
Common or Usual Name: Image Intensified Fluoroscopic X-ray System
Classification Name: Image Intensified Fluoroscopic X-ray System
Regulatory Class/ Regulation Number: Class II / 21 C.F.R. § 892.1650
Product Code: JAA/OXO

Intended Use / Indications for Use

The Trident Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

Device Description/ Technological Characteristics

The Trident Mobile Fluoroscopy System is a mobile Image Intensified Fluoroscopic X-ray unit with a flat panel image receptor system. The Trident Mobile Fluoroscopy System consists of the following components: an X- ray generator and tube housing and a flat panel detector. An X-ray cabinet contains system elements such as the X- ray generator, power electronics and electronics for the imaging chain. The system offers an optional monitor for viewing the captured images.

The X-Ray Generator is located in the base of the C-Arm. High voltage is carried to the X-Ray tube across a set of cables and the X-Ray tube emits the X-Rays that are directed toward the patient under the control of the operator. The X-Rays pass through the patient and are captured by the flat panel image detector (FPD). The flat panels used in the Trident Mobile Fluoroscopy System are Varex models 3030DX or 2121DXV. This Varex series have been used in similar cleared devices (K192541, K220871). The Varex flat panel system used in the Trident uses Cesium Iodide as the image scintillator which is identical to that used in the reference device (K220871). These flat panel models differ only in the dimensions of the image receptor. FPD images are processed and can be displayed on the optional image monitor located on the Workstation. The Physician or system operator can view the images as they are displayed on the attached monitor or they may also choose to store the images for later review via the connection to the hospital DICOM system.

The C-Arm is designed to move into the required positions to allow for proper x-ray locations in relation to the patient for the procedure that is being performed. These procedures can be performed with or without a patient table. In order to accomplish this, the system is designed with the ability to rotate/swivel to obtain different appropriate viewing angles.

The systems movement is manually adjusted with the exception of the z-axis. This is motorized with the controls on the C-arm. The release of x-ray is controlled using a footswitch and/or a hand controller.

The following table compares the technological characteristics of the Trident Mobile Fluoroscopy System and the primary predicate device.

	Trident Mobile Fluoroscopy System	**OEC 9900 Elite**	**Dornier Nautilus**
510(k) Number	Subject Device	Primary Predicate K120613	Reference Device K220871
Intended Use/ Indications for Use	The Trident Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic,· surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac; critical care and emergency room procedures.	The OEC® 9900 Elite Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic,· surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac; critical care and emergency room procedures.	The Dornier Nautilus is an image intensified, fluoroscopic x-ray system that is intended for use in a wide field of applications, including all general examinations in urology and gynecology, as well as endoscopic and contrast examinations, imaging with radiography and/or fluoroscopy on patients in either the horizontal or vertical position.
X-Ray Generator/Monoblock			
Input Power	115 / 230 V	120V,200V, 220V, 230V, 240V	480VAC
Power Rating (kW)	20 kW	15kW	80kW
Maximum kVp	120 kVp	120 kVp	150kVp
Maximum Rating (mA@kVp)	200mA	Up to 75mA	1000mA
kVp Range, radiographic	40 – 120kVp	40 – 120kVp	40-150kVp
mA Range, radiographic	Up to 200mA	Up to 75mA	10-1000mA
mAs Range	Up to 100	Up to 300	0.4-1000
kVp Range, Fluorographic	40 – 120kVp	40 – 120kVp	40-125kVp
mA Range, Fluorographic	Pulsed Fluoroscopy – up to 8mA (normal). HCF – up to 30mA	Pulsed Fluoroscopy 0.2 – 10mA normal 1.0 – 20mA HCF	Pulsed Fluoroscopy/HCF 16-80mA,

Fluoroscopy Capture Rate (frames/second)	With 2121 FPD – 0.5, 1, 2, 3, 4, 5, 6, 7.5, 12.5, 15 With 3030 FPD – 0.5, 1, 2, 3, 4, 5, 6, 7.5, 8, 12.5, 15, 25	1, 2, 4, 8	0.25-30
Digital Cine Mode	Yes	Yes	Yes
Digital Cine (frames/second)	With 2121 FPD – 0.5, 1, 2, 3, 4, 5, 6, 7.5, 12.5, 15 With 3030 FPD – 0.5, 1, 2, 3, 4, 5, 6, 7.5, 8, 12.5, 15, 25	Up to 30	Up to 30
X-ray Tube Housing			
X-Ray Tube Type	Rotating anode	Rotating anode	Rotating anode
Focal Size	0,3 mm and 0,6 mm	0.3mm and 0.6mm	1.2mm;: 0.6mm
Heat Capacity	2106 kJ	1200kJ	3500kJ
SID	1041mm	1041mm	1100-1250mm
X-ray Tube Retraction	none	none	Motorized
Collimator	RALCO R650/027/QDASM	Tungsten Collimator	RALCO R650 DAMS
Imaging	Flat Panel Detector	12” Image Intensifier	Flat Panel Detector
Manufacturer	Varex	GE/OEC	Varex
Model / Type	PAX SCAN 3030 DX OR 2121DXV	Tri-mode 12”/9”/6”	PAX SCAN 4343DXV
Image receptor/x-ray detection material	Amorphous Silicone/Cesium iodide		Amorphous Silicone/Cesium iodide
Maximum Active Area	3030 -298mm x 298mm 2121 – 209.9 x 209.9mm		42.7 x 42.7cm
Pixel Size	3030 - 194 µm 2121 - 205 µm		139 µm
Number of pixels (maximum detector matrix size)	3030 – 1536 x 1536 2121 – 1024 x 1024	1000k x 1000k CCD	3032 x 3032
Resolution	3030 – 2.58 lp/mm @ 15 fps 1.29 lp/mm @ 30 fps 2121 – 2.43 lp/mm @ 15 fps 1.22 lp/mm @ 30 fps	12”: 1.6 lp/mm 9”: 2.2 lp/mm 6”: 2.6 lp/mm	1.8 lp/mm @30fps 3.6 lp/mm @15fps
Dose Indicator	Display of applied dose in µGy		Display of applied dose in µGy
Image Processing			
Image Resolution	3030 – 1516 x 1516 2121 – 1004 x 1004	1000 x 1000	Up to 3072 x 3072
Image Processor	Technix	GE/OEC	Technix

Air Kerma Display	Calculated by Image processing SW Cumulative air kerma rate is shown on the monitors at the end of exposure Displays real time exposure rate		Calculated by Image processing SW Cumulative air kerma rate is shown on the monitors at the end of exposure Displays real time exposure rate
Image Storage Capacity	3030 – approx. 110,000 images 2121 – approx.. 250,000	1000	>110,000 images (depending on hard disk size and image file size)
Real-time Noise Reduction	Yes	Yes	Yes
Real-time Edge Enhancement	Yes	Yes	Yes
Network Connectivity DICOM 3.0	Yes	Yes	Yes

As demonstrated in the substantial equivalence table, the subject device, primary predicate, and reference devices have very similar technological characteristics. Any differences in technological characteristics are minor and do not raise new or different questions of safety or effectiveness. Performance data demonstrate that Dornier's Trident Mobile Fluoroscopy System is as safe and effective as the OEC 9900 Elite and Dornier Nautilus. Thus, the Trident Mobile Fluoroscopy System is substantially equivalent to the predicate and reference device.

Performance Data

The Trident Mobile Fluoroscopy System was tested in accordance to the FDA recognized consensus standards listed below:

These non-clinical tests were conducted on finished representative product and using the methods outlined in these standards. This performance testing confirmed that the Trident Mobile Fluoroscopy System contains all of the applicable requirements of the following standards:

Electrical Safety and EMC

- IEC 60601-1:2005, AMD1:2012,Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-6:2010+A1:2015, IEC 62366-2: 2007, A1:2014 Usability,
- IEC 60601-1-3:2008,A1:2013 1 Medical electrical equipment. Part 1: General requirements for safety; general requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54:2009, A1 2015,A2 2019 Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-2-43:2010 Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

- IEC 62304-2006/A1:2015 Software for Medical Devices Processes concerning software life cycle

Image Comparative Testing

Comparative images using the Trident Mobile Fluoroscopy System and the GE predicate device were taken to reflect usage conditions of the device. The images taken used a pelvic phantom as well as a Primus phantom. Upon review by a certified radiologic technologist, they were found to be clinically acceptable based on a comparison to the predicate GE device.

Software Verification and Validation Testing:

The software has been documented for an Enhanced Documentation Level (Moderate Level of Concern) per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023.

Clinical testing is not necessary for the Trident Mobile Fluoroscopy System as the subject device contains the same fundamental technology as the predicate device, as well as detectors that have already been cleared. Successful bench and image testing results demonstrate substantial equivalence to the predicate device.

The results of the non-clinical performance standard testing further supports the safe and effective use of the Trident Mobile Fluoroscopy System.

Substantial Equivalence/Conclusions

The Trident Mobile Fluoroscopy System and the predicate device have the same indications for use and intended use, and similar technological characteristics and principles of operation. The minor technological differences between the Trident Mobile Fluoroscopy System and the predicate device do not present new or different questions of safety or effectiveness. Furthermore, performance testing has demonstrated that the subject device is as safe and effective as the predicate device. In addition, the subject and predicate device have similar principles of operation. Thus, the Trident Mobile Fluoroscopy System is substantially equivalent to the predicate device.