April 18, 2022

Dornier MedTech America, Inc.
% Mr. John Hoffer
VP Quality, Regulatory, Clinical
1155 Roberts Blvd., Suite 100
KENNESAW GA 30144

Re: K220871
Trade/Device Name: Nautilus
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: March 24, 2022
Received: March 25, 2022

Dear Mr. 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 (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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220871

Device Name
Nautilus

Indications for Use *(Describe)*

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.

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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510(k) SUMMARY

Dornier's Nautilus

Submission #: K220871

Submitter

Dornier MedTech America Phone: 770-514-6163

1155 Roberts Blvd. Fax: 770-514-6291

Kennesaw, GA 30144

Date Prepared: April 12, 2022

Contact Person: John Hoffer Phone: 770-514-6163

Name of Device: Nautilus
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 Dornier Genesis (K151485)
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

Intended Use / Indications for Use

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.

Device Description/ Technological Characteristics

The Dornier Nautilus is an Image Intensified Fluoroscopic X-ray System with a flat panel image receptor system. The Nautilus consists of the following components: an X- ray generator and tube housing, flat panel detector, monitors and procedure table. An X-ray cabinet contains system elements such as the X-ray generator, power electronics and electronics for the imaging chain.

The Dornier Nautilus is a radiographic and fluoroscopy examination table with the X-ray tube housing mounted under the table on a fixed arm. A flat panel detector is mounted above the patient table. The flat panel used is a Varex model 4343DXV. These Varex 4343 series have been used in similar cleared devices (K192541). The Varex flat panel system uses Cesium Iodide as the image scintillator which is identical to that used in the predicate device. While the X-ray tube and detector are fixed in their positions relative to each other when the system is in use, the table top and X-ray/detector unit can be moved in a variety of planes to position the patient in the desired imaging position. The captured images are processed and can be stored in the users DICOM system.

Performance Data

The Nautilus follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:

Non-clinical tests were conducted during product development. Performance testing confirmed that the Nautilus met the 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 60601-1-6:2010,A1:2013 Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
- IEC 60601-2-28:2017 Medical electrical equipment. Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- 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

Software Verification and Validation Testing:

The software used in the Nautilus has the identical functionality as in the predicate Genesis device. Documentation for a Moderate Level of Concern per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on November 4, 2021 is also included as part of this submission.

Clinical testing is not necessary for the subject system Nautilus, based on the same basic technology as the predicate device and based on existing minor differences. Successful bench testing results should demonstrate substantial equivalence to the predicate device Genesis.

The results of the non-clinical performance standards testing support that the device can be used safely and effectively.

Substantial Equivalence/Conclusions

The Nautilus and the Genesis predicate device have the same intended use and indications, technological characteristics and principles of operation. The minor technological differences between the Nautilus and its predicate do not present 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 devices have similar principles of operation. Thus, the Nautilus is substantially equivalent to the predicate device