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December 23, 2024

NRT X-Ray A/S
% Mogens Ravn
Managing Director
Birkegaardsvej 16
8361 Hasselager
Denmark

Re: K242948
Trade/Device Name: Adora DRFi
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA
Dated: September 25, 2024
Received: September 25, 2024

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Dear Mogens Ravn:

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.

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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242948

Device Name

Adora DRFi

Indications for Use *(Describe)*

The Adora DRFi is a direct radiography and radioscopy, universal and permanently installed diagnostic X-ray system with a flat panel detector, which allows the acquisition of a wide range of X-ray examinations. It is intended for use in generating diagnostic radiographic and radioscopic images of human anatomy. The Adora DRFi X-ray system is intended for use by trained and qualified personnel at the entire body of both adult and pediatric patients, and exposures may be acquired with the patient in supine, standing or sitting positions as well as with the patient in e.g., a wheelchair or on a stretcher. Radiographic procedures can take place with the detector in free position as well as fixed in the docking station; whereas radioscopic procedures may only take place when the detector is fixed in the docking station.
The Adora DRFi is not for mammography examinations.

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

This summary document has been prepared to meet the conditions of 21 CFR 807.92.

| | |
|---|---|
| Date of summary: | Dec. 23, 2024 |

**Subject device:**

| | |
|---|---|
| Trade name: | **Adora DRFi** |
| Classification name: | Image-intensified fluoroscopic x-ray system |
| Classification: | Class II |
| CFR Section: | 892.1650 |
| Product Code: | JAA |

**Manufacturer:**

| | |
|---|---|
| Company name: | NRT X-RAY A/S |
| Address: | Birkegaardsvej 16<br>8361 Hasselager<br>Denmark |
| Phone no.: | +45 8628 3500 |
| E-mail: | nrt@nrtxray.com |
| Contact person: | Mogens Ravn |
| Phone no.: | +45 5123 0330 |
| E-mail: | mr@nrtxray.com |

**Predicate device:**

| | |
|---|---|
| Trade name: | **Siemens Multitom Rax** |
| Classification name: | Image-intensified fluoroscopic x-ray system |
| Classification: | Class II |
| CFR Section: | 892.1650 |
| Product Code: | OWB, JAA |
| Premarket Notification No.: | K152928 |
| Manufacturer: | SIEMENS AG Sector Healthcare<br>Siemensstraße 1<br>D-91301 Forchheim, Germany |

**Device description for new device:**

The Adora DRFi x-ray system is a ceiling suspended universal x-ray system using direct radiography and radioscopy on flat panels for diagnostic purposes. The system can be used for acquisition of a wide range of radiographic and radioscopic x-ray examinations of the whole body, on both adult and pediatric patients. The patients may be lying on the Adora table, in a hospital bed or on a stretcher, using the flat panel's ability to be placed either inside or outside its housing for radiographic examinations. Radioscopic examinations, however, can only be made with the flat panel in the housing suspended in one of the two telescopes. The

patients may also be standing on the floor, sitting on a chair or in a wheelchair. Examples of examinations which can be performed on Adora X-ray systems; Radiography for Pelvis Supine, Pelvis Standing, Knee, and Radioscopy for Esophagus, Tube placement, knee.
The positioning of the ceiling suspended X-ray tube and the flat panel relative to the patient and each other are controlled by the operator, either through a joystick or via pre-programmed auto-positions activated by the operator.
The Adora X-ray system is a main powered, permanently installed system for use in hospitals and x-ray clinics and is intended solely for use by healthcare professionals, trained in and qualified for the use of medical x-ray equipment for diagnostic purposes.

The Adora DRFi device will be offered in one main variant:

| **NRT REF No.:** | **Device name:** |
|---|---|
| 04550010 | Adora DRFi |

**Electrical safety, EMC and QMS:**
The Adora DRFi device conforms to applicable international standards such as IEC 60601-1 including collateral and particular standards, and FDA performance standards 21 CFR 1020.30, 31 and 32. Design and production controls are carried out under a Quality Management System in compliance with 21 CFR 820 and ISO 13485 requirements

The following applied standards have been used developing the Adora DRFi device:

| Standard no. | Standard title | FDA recognition no. | Version | Date |
|---|---|---|---|---|
| IEC 60601-1 Edition 3.2 (2020) | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance + US national differences | 19-49 | Edition 3.2 | (2020-08) |
| IEC 60601-1-2 Edition 4.1 (2020) | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic disturbances - Requirements and tests | 19-36 | Edition 4.1 | (2020-09) |
| IEC 60601-1-3 Edition 2.2 (2021) | Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment | 12-336 | Edition 2.2 | (2021-01) |
| 60601-1-6 Edition 3.2 (2020) | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability | 5-132 | Edition 3.2 | (2020-07) |
| IEC 60601-2-54 Edition 2.0 (2022) | Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy | 12-348 | Edition 2.0 | (2022-09) |

# 510(k) Summary

| Standard no. | Standard title | FDA recognition no. | Version | Date |
|---|---|---|---|---|
| IEC 60825-1 Edition 3 (2014) | Safety of laser products - Part 1: Equipment classification and requirements | 12-273 | Edition 3.0 | (2014-05) |
| IEC 62304 Edition 1.1 (2015) | Medical device software - Software life-cycle processes | 13-79 | Edition 1.1 | (2015-06) |
| IEC 62366-1 Edition 1.1 (2020) | Medical devices - Part 1: Application of usability engineering to medical devices | 5-129 | Edition 1.1 | (2020-06) |
| 21CFR Part 1020 All applicable sections | FDA Performance Standards for Ionizing Radiation Emitting Products | N/A | N/A | N/A |
| ISO 10993-1: 2018 (EN ISO 10993-1:2020) | Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process | 2-258 | Edition 5 | (2018-08) |
| ISO 10993-10: 2010 (EN ISO 10993-10:2013) | Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization | 2-174 | Edition 3 | (2010-08) |
| EN ISO 13485:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes | N/A | Edition 3 | (2016-03) |
| 21CFR Part 820 | FDA Quality System Regulation | N/A | N/A | N/A |
| EN ISO 14971:2019 | Medical Devices – Application of risk management to medical devices | 5-125 | Edition 3 | (2019-12) |
| EN ISO 15223-1:2021 | Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements | 5-134 | Edition 4 | (2021-07) |
| DS/EN ISO 20417:2021 | Information to be supplied by the manufacturer | 5-135 | Edition 1 | (2021-12) |

## FDA guidance documents used for this submission:

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| FDA Software Guidance: "Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff," dated June 2023 |
| FDA Cybersecurity Guidance: "Cybersecurity in Medical Devices: Quality System Considerations and content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff," dated September 27, 2023 |
| FDA Pediatric Guidance: "Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff," dated November 2017. |

## Comparison with predicate device:

The Adora DRFi and Siemens Multitom Rax are very similar in all comparable parameters. The predicate device comparison in "Technilogical Differences" section of this summary, contains a comparison between the Adora DRFi and its predicate device, the Siemens Multitom Rax.
For the purpose of this 510(k) Summary, please find a comparison of the indications for Use, target population and selected technology aspects below:

**Comparison table, Indications for Use and target population:**

| | Adora DRFi | Multitom Rax |
|---|---|---|
| **Indications for use:** | The Adora DRFi is a direct radiography and radioscopy, universal and permanently installed diagnostic x-ray system with a flat panel detector, which allows the acquisition of a wide range of x-ray examinations. It is intended for use in generating | The Multitom RAX is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations. The Multitom |

| | | |
|---|---|---|
| | diagnostic radiographic and radioscopic images of human anatomy. The Adora DRFi x-ray system is intended for use by trained and qualified personnel at the entire body of both adult and pediatric patients, and exposures may be acquired with the patient in supine, standing or sitting positions as well as with the patient in e.g., a wheelchair or on a stretcher. Radiographic procedures can take place with the detector in free position as well as fixed in the docking station; whereas radioscopic procedures may only take place when the detector is fixed in the docking station.<br>The Adora DRFi is not for mammography examinations. | RAX is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image.<br>The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The unit may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiography, digital angiography and digital subtraction angiography (DSA). The Multitom RAX may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations. The Multitom RAX is not for mammography examinations. |
| **Target population:** | Adults and pediatrics | Adults and pediatrics |

**Technological differences:**

Both the Adora DRFi and the Siemens Multitom Rax are stationary X-ray systems for radiography and fluoroscopy. They consist of a floor mounted patient table and ceiling suspended X-ray tube and a ceiling suspended flat panel detector. Together with an X-ray generator and a digital imaging system they provide comprehensive image acquisition modes to support radiographic and fluoroscopic imaging procedures. X-ray tube and flat panel detector movements are synchronized to provide rotation around a center.

The Adora DRFi utilizes the Canon CXDI-RF Wireless B1 with the Canon CXDI imaging software for image acquisition and post processing, previously cleared under K232298.

| Data category | Adora DRFi | Siemens Multitom Rax |
|---|---|---|
| **General design** | Patient table with floating top, height adjustable and with an optional 340° rotation around the base ensures easy patient access all around the table. Suitable for access with wheelchairs and beds and provides optimal cleaning conditions. | Height-adjustable table with table height of 50 cm. 360° patient access, including equipment for interventions. |
| **Detector** | **Model**<br>**Canon CXDI-RF Wireless B1 (FDA K232298)**<br>Technology: a-Si / CsI<br>Active area: 43 x 42 cm<br>Pixel array: 160 microns | **Model**<br>**RAXdetector**<br>Technology: a-Si / CsI<br>Active area: 43 x 42 cm<br>Pixel array: 148 microns |
| **Generator** | **Model**<br>**CPI Indico IQ, 80kW** | **Model**<br>**Siemens Polydoros F80, 80kW** |
| **Generator performance** | **Fluoroscopy**<br>40 kV to 125 kV / 5 mA to 99 mA Pulsed fluoro<br><br>**Radiography**<br>40 kV to 150 kV | **Fluoroscopy**<br>40 kV to 110 kV / 4 mA to 84 mA Pulsed fluoro<br><br>**Radiography**<br>40 kV to 150 kV |
| **Imaging modalities** | Radiography<br>Fluoroscopy<br>Cine<br>3D image acquisition | Radiography<br>Fluoroscopy<br>Cine<br>DSA (roadmap)<br>3D image acquisition and reconstruction |
| **Technical data** | **Positioning:** | **Positioning:** |

| | | |
|---|---|---|
| | Up to 999 APRs and associated auto-positions with all image acquisition parameters can be programmed to match users' preferences. | The system can move into more than 1000 pre-defined positions. |
| **Tabletop** | **Tabletop size:**<br>Width: 70 cm<br>Length: 293 cm<br>Material: Carbon fiber<br><br>**Tabletop movement:**<br>Longitudinal: ± 10 cm<br>Transverse: ± 20 cm<br><br>**Tabletop movement:**<br>Vertical movement: 57 to 92 cm.<br>Table rotation: ± 340° (optional)<br><br>**Max. table load:** 250 kg. | **Tabletop size:**<br>Width: 75 cm<br>Length: 219 cm<br>Material: Carbon fiber<br><br>**Tabletop movement:**<br>Longitudinal: N/A (fixed)<br>Transverse: N/A (fixed)<br><br>**Tabletop movement:**<br>Vertical movement: 50 to 92 cm.<br>Table rotation: 0°.<br><br>**Max. table load:** 240 kg. |

**Comparison table, Design, Modality and Technology**

**Conclusions:**

Based upon the above information we believe that the Adora DRFi is substantially equivalent to the predicate device in that, though there are minor difference, the Indication for Use statement is functionally the same and the intended use of the device is in line with the predicate Siemens Multitom Rax. Testing demonstrates that this device will perform in a manner that is as safe and effective or better than the predicate device. The major difference between the two systems is related to the design of components and that the data and information provided supports a decision of substantial equivalence. The differences between the systems are mainly due to the difference in design philosophy. The Adora system has been developed with the specific aim of improving ergonomics and workflow, while the Siemens competitor is more traditional in their approach. However, the differences in specifications are small and both systems are capable of a similar range of examination procedures. Our conclusion is that new issues of safety or effectiveness are not raised with the introduction of the Adora DRFi device.