July 26, 2024

DRTECH Corporation
% Kim Hanbyul
Assistant Manager
Suite No. 1, 2 Floor/Suite No. 2, 3 Floor, 29, Dunchon-Daero
541 Beon-Gil Jungwon-Gu
Seongnam-si, Gyeonggi-do 13216
SOUTH KOREA

Re: K233530
Trade/Device Name:

EXSYS DEXi (EXSYS DEXi-D401S-FRM);
EXSYS DEXi (EXSYS DEXi-A401S-FRM);
EXSYS DEXi (EXSYS DEXi-D402S-FRM);
EXSYS DEXi (EXSYS DEXi-A402S-FRM);
EXSYS DEXi (EXSYS DEXi-D401P-FRM);
EXSYS DEXi (EXSYS DEXi-A401P-FRM);
EXSYS DEXi (EXSYS DEXi-D402P-FRM);
EXSYS DEXi (EXSYS DEXi-A402P-FRM);
EXSYS DEXi (EXSYS DEXi-D503T-FRM);
EXSYS DEXi (EXSYS DEXi-A503T-FRM)

Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: June 27, 2024
Received: June 27, 2024

Dear Kim Hanbyul:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233530

Device Name

EXSYS DEXi (EXSYS DEXi-D401S-FRM);
EXSYS DEXi (EXSYS DEXi-A401S-FRM);
EXSYS DEXi (EXSYS DEXi-D402S-FRM);
EXSYS DEXi (EXSYS DEXi-A402S-FRM);
EXSYS DEXi (EXSYS DEXi-D401P-FRM);
EXSYS DEXi (EXSYS DEXi-A401P-FRM);
EXSYS DEXi (EXSYS DEXi-D402P-FRM);
EXSYS DEXi (EXSYS DEXi-A402P-FRM);
EXSYS DEXi (EXSYS DEXi-D503T-FRM);
EXSYS DEXi (EXSYS DEXi-A503T-FRM)

Indications for Use *(Describe)*

The EXSYS DEXi is a diagnostic X-ray system intended for use in generating radiographic images of human anatomy for general purpose. The system obtains necessary information of patient's anatomical structure by an image processing (workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.

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

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

11/01/2023

2. Submitter's Information [21 CFR 807.92(a) (1)]

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216, Republic of Korea
- Contact Name: Hanbyul Kim
- Telephone No.: + 82-31-779-7720
- Fax No.: + 82-31-779-7790
- Email Address : drtechra@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

- Trade(Brand) Name: EXSYS DEXi
- Device(Model) Name : EXSYS DEXi (EXSYS DEXi-D401S-FRM);
  EXSYS DEXi (EXSYS DEXi-A401S-FRM);
  EXSYS DEXi (EXSYS DEXi-D402S-FRM);
  EXSYS DEXi (EXSYS DEXi-A402S-FRM);
  EXSYS DEXi (EXSYS DEXi-D401P-FRM);
  EXSYS DEXi (EXSYS DEXi-A401P-FRM);
  EXSYS DEXi (EXSYS DEXi-D402P-FRM);
  EXSYS DEXi (EXSYS DEXi-A402P-FRM);
  EXSYS DEXi (EXSYS DEXi-D503T-FRM);
  EXSYS DEXi (EXSYS DEXi-A503T-FRM)
- Common Name: Diagnosis X-Ray System
- Classification Name: Stationary x-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1680
- Product Code: KPR
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

- 510(k) Number: K202572
- Applicant: DRGEM Corporation
- Trade Name: GXR-Series Diagnostic X-Ray System
- Classification Name: Stationary x-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 892.1680
- Product Code: KPR
- Device Class: II

5. Description of the Device [21 CFR 807.92(a) (4)]

The EXSYS DEXi is a diagnostic X-ray system intended for use in generating radiographic images of human anatomy for general purpose. The system obtains necessary information of patient's anatomical structure by an image processing (workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.

The EXSYS DEXi composed of a x-ray generator, tube, collimator, tube stand, bucky stand, patient table, flat panel detector and console.

The operation principle of the device involves utilizing the X-ray generator, based on examination parameters set by the user such as tube voltage, tube current, exposure time to irradiate the specific area of the patient being examined with X-rays. The X-rays that have been emitted are then processed into images through a detector after passing through the patient.

6. Indication for Use [21 CFR 807.92(a)(5)]

The EXSYS DEXi is a diagnostic X-ray system intended for use in generating radiographic images of human anatomy for general purpose. The system obtains necessary information of patient's anatomical structure by an image processing (workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device [21 CFR 807.92(a)(6), 21 CFR 807.92(b)]

The EXSYS DEXi composed of a x-ray generator, tube, collimator, tube stand, bucky stand, patient table, flat panel detector and console.

It is a diagnostic X-ray system intended for use in generating radiographic images of human anatomy for general purpose. The system obtains necessary information of patient's anatomical structure by an image processing (workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.

The subject device has the same fundamental scientific technologies as the predicate devices. The technological comparison table below demonstrates the comparability of the technological characteristics of the new device and the currently cleared predicate devices. The Technological differences do not affect the intended use of the device.
The table 1 below compares the main performance data of the subject device with the predicate devices to substantiate equivalence of the subject device and predicates.

Table 1. Comparison of the Subject Device to the Predicate Device Substantial Equivalence

Parameter	Subject Device	Predicate Device	Discussion
510(K) Number	Unknown	K202572	N/A
Manufacturer	DRTECH Corporation	DRGEM Corporation	N/A
Device/ Brand Name	EXSYS DEXi	GXR-Series Diagnostic Imaging System	N/A
Model Name	EXSYS DEXi-D401S-FRM EXSYS DEXi-A401S-FRM EXSYS DEXi-D402S-FRM EXSYS DEXi-A402S-FRM EXSYS DEXi-D401P-FRM EXSYS DEXi-A401P-FRM EXSYS DEXi-D402P-FRM EXSYS DEXi-A402P-FRM EXSYS DEXi-D503T-FRM EXSYS DEXi-A503T-FRM	GXR-SD/CSD/USD	N/A
Classification Name	Stationary x-ray system	Stationary x-ray system	Identical
Classification Regulation	21 CFR 892.1680	21 CFR 892.1680	Identical
Product Code	KPR	KPR	Identical
Device Class	Class II	Class II	Identical
Intended Use	The EXSYS DEXi is a diagnostic X-ray system intended for use in generating radiographic images of human anatomy for general purpose. The system obtains necessary information of patient's anatomical structure by an image processing (workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.	GXR-Series Diagnostic X-Ray System, is a stationary X-ray imaging system, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography or bone density applications.	Similar The intended use of both the subject device and the predicate device is to generate radiographic images of human anatomy for diagnostic purposes. Both systems have a general-purpose application, using radiation exposure to capture images of a patient's anatomical

			structure, which are then processed using an image processing workstation. Neither device is intended for mammography or bone density applications. Therefore, the differences in the intended use between the two products do not introduce any new intended use for the device, and these differences do not affect a decision of substantial equivalence.
High Frequency X- ray Generator			
Output Power	40kW, 50kW	32KW, 40KW, 52KW, 68KW, 82KW	-
Generator models	DXG-40S, DXG-40P, DXG-50T	GXR-32, GXR-40, GXR-52, GXR-68, GXR-82 GXR-C32, GXR-C40, GXR-C52	-
Line voltage	DXG-40S, DXG-40P : 220~230VAC DXG-50T : 230/380/400/480VAC	220~230VAC 380/400/480VAC	Although there are some differences in ratings, the system has been tested and there is "No negative impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.
kV Range	DXG-40S, DXG-40P : 40~125kV, 1kV step DXG-50T : 40~150kV, 1kV step	40~125kV, 1kV step (Optional 40~150kV)	Identical
mA Range	DXG-40S, DXG-40P : 10 to 500mA DXG-50T : 10 to 630mA	GXR-32=10 to 400mA GXR-40=10 to 500mA GXR-52=10 to 640mA GXR-68=10 to 800mA GXR-82=10 to 1,000mA	Although there are some differences in mA range, the system has been tested and there is "No negative impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.
Image Acquisition			
Detector	Used with DRTECH Detector K193017 :	VAREX, 4343R v3 - K172951 VAREX, 4336W v4- K161459	The system has been tested and there is "No negative impact on safety or efficacy" and

	EVS 4343W, EVS 4343WP, EVS 3643W, EVS 3643WP K192400 : EVS 4343A, EVS 3643A K193031 : EX PD 4343P, EXPD 3643P K223124 : EXPD 86P, EXPD 86PG, EXPD 129P, EXPD 129PG	VAREX, XRpad2 3025 HWC-M- K161942 VAREX, XRpad2 4336 HWC-M- K161966 VAREX, XRpad2 4343 HWC-M- K181526 i-Ray, Mano4336W- K201004 i-Ray, Mano4343W- K201043 Vieworks, VIVIX-S1417N (NAW, NBW)-K163703 Vieworks, VIVIX-S1717N (NAW, NBW)- K152894 VAREX, 4343W- K161459	there are no new potential or increased safety risks concerning this difference. All the flat panel detectors have been previously cleared by 510(k).
Image Management Software			
Software	EConsole1(K231225)	RADMAX (K182537)	Software has been previously cleared by 510(k). .
Image viewing	Available	Available	Identical
Image search	Available	Available	Identical
Image storage	Available	Available	Identical
Image annotation	Available	Available	Identical
Image measurement	Available	Available	Identical
Image processing	Available	Available	Identical
Image stitch	Available	Available	Identical
Generator Control	Available	Available	Identical

There are no significant differences between the EXSYS DEXi and the predicate device that would have a negative impact on the product's use. Therefore, the subject device is considered substantially equivalent to the predicate device.

9. Summary of Non-Clinical Data [21 CFR 807.92(b)(1)]

The EXSYS DEXi comply with the following international and FDA-recognized consensus standards list in Table 2.

Table 2. International and FDA-recognized consensus standards

Standards development organization, reference number, and date	Standard name
ISO 14971: Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
UL ANSI 2900-1 First Edition 2017	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements
IEC 81001-5-1 Edition 1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

And EXSYS DEXi comply with the FDA guidance documents listed in Table 3.

Table 3. FDA Guidance Documents

Title of Guidance Document	Issue Date
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff	June 14, 2023
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray Imaging Devices Conformance with IEC Standards	May 8, 2019
Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions	September 27, 2023
Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff	November 28, 2017

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

10. Summary of Clinical Data [21 CFR 807.92(b)(2)]

Not Applicable
Clinical studies are unnecessary to validate the safety and effectiveness of the Stationary x-ray system, EXSYS DEXi, the subject of this 510(k) notification.

11. Conclusion [21 CFR 807.92(b)(3)]

The EXSYS DEXi is substantially equivalent to the currently marketed predicate device (GXR-Series Diagnostic X-Ray System (K202572)) in terms of technical characteristics, general function, application and indications for use, safety, and effectiveness.

Substantial equivalence for Stationary X-ray System(EXSYS DEXi) was demonstrated through the non-clinical performance in compliance with the requirements specified in the international and FDA recognized consensus standards, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62366-1, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, IEC 62304 and ANSI UL 2900-1.

The comparison of technological characteristics, non-clinical performance data and safety testing demonstrate that the EXSYS DEXi is substantially equivalent to the predicate devices.