October 23, 2024

DRTECH Corporation
% Hanbyul Kim
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: K242847
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); EXSYS DEXi (EXSYS DEXi-D401S-FRA); EXSYS DEXi (EXSYS DEXi-D402S-FRA); EXSYS DEXi (EXSYS DEXi-D401P-FRA); EXSYS DEXi (EXSYS DEXi-D402P-FRA); EXSYS DEXi (EXSYS DEXi-D503T-FRA)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: September 20, 2024
Received: September 20, 2024

Dear Hanbyul Kim:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic 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)*

K242847

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);
EXSYS DEXi (EXSYS DEXi-D401S-FRA);
EXSYS DEXi (EXSYS DEXi-D402S-FRA);
EXSYS DEXi (EXSYS DEXi-D401P-FRA);
EXSYS DEXi (EXSYS DEXi-D402P-FRA);
EXSYS DEXi (EXSYS DEXi-D503T-FRA)

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.

510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number: K242847

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)]

09/20/2024

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);
  EXSYS DEXi (EXSYS DEXi-D401S-FRA);
  EXSYS DEXi (EXSYS DEXi-D402S-FRA);
  EXSYS DEXi (EXSYS DEXi-D401P-FRA);
  EXSYS DEXi (EXSYS DEXi-D402P-FRA);
  EXSYS DEXi (EXSYS DEXi-D503T-FRA);

- 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: K233530
- Applicant: DRTECH Corporation
- 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);
- 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.

Although it shares the same brand name as the predicate device EXSYS DEXi (K233530), a model name has been added with the following modifications:

1) Addition of collimator
2) Addition of mechanical parts (tube stand, bucky stand, patient table)
3) Addition of a detector
4) Addition of software
5) Update of software

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	K233530	N/A
Manufacturer	DRTECH Corporation	DRTECH Corporation	N/A
Device/ Brand Name	EXSYS DEXi	EXSYS DEXi	N/A
Model Name	EXSYS DEXi-A401S-FRM EXSYS DEXi-A402S-FRM EXSYS DEXi-A401P-FRM EXSYS DEXi-A402P-FRM EXSYS DEXi-A503T-FRM EXSYS DEXi-D401S-FRM EXSYS DEXi-D402S-FRM EXSYS DEXi-D401P-FRM EXSYS DEXi-D402P-FRM EXSYS DEXi-D503T-FRM EXSYS DEXi-D401S-FRA EXSYS DEXi-D402S-FRA EXSYS DEXi-D401P-FRA EXSYS DEXi-D402P-FRA EXSYS DEXi-D503T-FRA	EXSYS DEXi-A401S-FRM EXSYS DEXi-A402S-FRM EXSYS DEXi-A401P-FRM EXSYS DEXi-A402P-FRM EXSYS DEXi-A503T-FRM EXSYS DEXi-D401S-FRM EXSYS DEXi-D402S-FRM EXSYS DEXi-D401P-FRM EXSYS DEXi-D402P-FRM EXSYS DEXi-D503T-FRM	Model names have been added due to the addition of product configurations. 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.
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	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	Identical

	(workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.	(workstation) after process of examination using radiation exposure with DR. This system is not intended for mammography applications.	
High Frequency X- ray Generator			
Output Power	40kW, 50kW	40kW, 50kW	Identical
Generator models	DXG-40S DXG-40P DXG-50T	DXG-40S DXG-40P DXG-50T	Identical
Line voltage	DXG-40S, DXG-40P : 220~230VAC DXG-50T : 230/380/400/480VAC	DXG-40S, DXG-40P : 220~230VAC DXG-50T : 230/380/400/480VAC	Identical
kV Range	DXG-40S, DXG-40P : 40~125kV, 1kV step DXG-50T : 40~150kV, 1kV step	DXG-40S, DXG-40P : 40~125kV, 1kV step DXG-50T : 40~150kV, 1kV step	Identical
mA Range	DXG-40S, DXG-40P : 10 to 500mA DXG-50T : 10 to 630mA	DXG-40S, DXG-40P : 10 to 500mA DXG-50T : 10 to 630mA	Identical
Image Acquisition			
Detector	Used with DRTECH Detector K193017 : EVS 4343W, EVS 4343WP, EVS 3643W, EVS 3643WP K192400 : EVS 4343A, EVS 3643A K193031 : EXPD 4343P, EXPD 3643P K223124 : EXPD 86P, EXPD 86PG, EXPD 129P, EXPD 129PG K231959 : EXPD 4357, EXPD 4357P K232082 : EXPD 4343S K232753 : EXPD 3643D, EXPD 4343D	Used with DRTECH Detector K193017 : 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	510(k) cleared detectors have been added. 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. All the flat panel detectors have been previously cleared by 510(k).
Image Management Software			
Software	EConsole1 (K231225) EConsole2 (K240243)	EConsole1 (K231225)	Added our software, EConsole2 (K240243), which was previously cleared with 510(k). 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 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
X-ray Tube			
Tube models	E7239X, E7242X, E7884X	E7239X, E7242X, E7884X	Identical
Max. Tube Voltage	E7239X : 125 kV E7242X : 125 kV E7884X : 150 kV	E7239X : 125 kV E7242X : 125 kV E7884X : 150 kV	Identical
Anode Heat Capacity	E7239X : 140 kHU E7242X : 200 kHU E7884X : 300 kHU	E7239X : 140 kHU E7242X : 200 kHU E7884X : 300 kHU	Identical
Collimator			
Collimator Models	M-38 R 221/A DHHS R 225 ACS DHHS	M-38	A new collimator that operates manually and another type that operates automatically have been added. We have conducted tests regarding the addition of these collimators, and there is "no negative impact on safety or efficacy." Furthermore, there are no new potential risks or increased safety hazards related to these differences.
Adjustment method	Manual, Auto	Manual	
Tube Stand			
Models	DTS-M DTS-A	DTS-M	Motorized tube stand has been added. We have conducted tests regarding this addition, and there is "no negative impact on safety or efficacy." Furthermore, there are no new potential risks or increased safety hazards related to these differences.
Operation Method	Manual, Auto	Manual	

Type	Floor-supported type	Floor-supported type	Identical
Tube Head Console	Membrane OP LCD Console	Membrane OP LCD Console	Identical
Bucky Stand			
Models	DBS-43M LLD 129 With Rotation LLD 129 Compact DBS-57M DBS-43A DBS-57A	DBS-43M LLD 129 With Rotation LLD 129 Compact	Three Types of bucky stands have been added. We have conducted tests regarding this addition, and there is "no negative impact on safety or efficacy." Furthermore, there are no new potential risks or increased safety hazards related to these differences.
Operation Method	Manual, Auto	Manual	
Type	Floor-supported type	Floor-supported type	Identical
Patient Table			
Models	DPT-4A DPT-6A DPT-4B DPT-6B DPT-6AT DPT-6BT	DPT-4A DPT-6A	Four Types of patient tables have been added. We have conducted tests regarding this addition, and there is "no negative impact on safety or efficacy." Furthermore, there are no new potential risks or increased safety hazards related to these differences.
Type	4 way : DPT-4A, DPT-4B 6 way : DPT-6A, DPT-6B, DPT-6AT, DPT-6BT	4 way : DPT-4A 6 way : DPT-6A	
Fixed method	Electromagnet	Electromagnet	Identical

There are no significant differences between the subject Device 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
IEC 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
Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff	Nov 28, 2017
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray Imaging Devices Conformance with IEC Standards	May 8, 2019
Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff	June 14, 2023
Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions	Sep 27, 2023

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 (K233530) 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, IEC 81001-5-1 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.