Adani
℅ Vladimir Linev
CEO & General Director
7 Selitsky str.
Minsk, 220075
BELARUS

May 26, 2020

Re: K200944
Trade/Device Name: UNIEXPERT 2 PLUS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: April 8, 2020
Received: April 8, 2020

Dear Vladimir Linev:

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,

For

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K**200944**

Device Name
UNIEXPERT 2 PLUS

Indications for Use *(Describe)*

The UNIEXPERT 2 PLUS is a stationary general-purpose radiographic imaging system indicated for use in acquiring diagnostic X-Ray images of osseous structures and soft tissues of the human body to aid physicians with patient diagnosis. The system has analogue, computed radiography (CR) as well as digital radiography (DR) imaging capabilities. The UNIEXPERT 2 PLUS is not indicated for use in mammography.

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
K200944

The following 510(k) Summary is submitted in accordance with the requirements as set forth in 21 CFR Part 807.92.

Submitter Name:	Adani Establishment Registration Number: 3004718499
Address:	Adani 7 Selitsky Str. Minsk, 220075
Telephone Number:	+375 (17) 349-00-00
Contact Person:	Vladimir Linev, CEO & General Manager
Date Prepared:	March 6, 2020

Subject Device:

Device Trade Name:	UNIEXPERT 2 PLUS
Device Common Name:	Digital X-Ray Imaging System
Device Classification	Stationary X-Ray System
Regulation	892.1680
Name: Device Class:	Class II
Product Code:	90 KPR

Predicate Device:

Device Trade Name:	Q-Rad Radiographic System (K011486)
Device Common Name:	Digital X-Ray Imaging System
Device Classification Name:	Stationary X-Ray System
Regulation	892.1680
Device Class:	Class II
Product Code:	90 KPR

Device Description:

The UNIEXPERT 2 PLUS is a diagnostic X-Ray system intended for radiographic imaging of osseous structures and soft tissues of the human body. The system may be used for analogue film imaging as well as digital image acquisition.

The UNIEXPERT 2 PLUS is comprised of an X-Ray generator with user interface, X-Ray tube, beam limiting device, vertical column tube stand, radiographic table, vertical wall stand, digital X-Ray image detector.

The following table contains the specific components for the UNIEXPERT 2 PLUS. A complete system is comprised of a component from each category and may include more than one grid and more than one detector. All detectors are previously-cleared by FDA.

Generator	X-Ray Power Supply (high voltage generator) CMP200, model: VZW2556RE2-90
	X-Ray Power Supply (high voltage generator) CMP200 DR, model: VZW2556RB2-KK
	X-Ray Power Supply (high voltage generator) CMP200 DR, model: VZW2556RE2-96
	RAD/FLUORO INDICO IQ 50 kW 150 kV 400VAC
	RAD/FLUORO INDICO IQ 65 kW 150 kV 400VAC
	RAD/FLUORO INDICO IQ 80 kW 150 kV 400VAC
User Interface	USER AUTOMATED WORK STATION (AWS)
Tube Stand	ADN114.13.00.000
Wall Stand	ADN114.14.00.000
Patient Table	ADN114.11.00.000
AEC	Solid State Measuring Chamber 610
Grids	MG05870002AP135AS
	MG05870002AP200AS
	MG05870002AR200AS
	ACS AL (48 см x 44 см; 80 л/см; 12:1; f=100 см)
	ACS AL (48 см x 44 см; 80 л/см; 12:1; f=150 см)
	G_480X440MM_40L/CM_12_100CM_AS
Detectors	Varex PaxScan 4336W v4 (K171138); PaxScan 4343R v3 (K172951)
	Perkin Elmer, XPRAD2 4336 (K161966)
	Vieworks FXRD-1417NAW (K163703)
Beam Limiting Device	Ralco R 225
	Ralco R 302/A
	Siemens ML03
	Siemens ML04
X-Ray Tube	X-Ray Tube C352-RTM 78 HS F:0.6/1.2
	X-Ray Tube C352-RTM 782 HS F:0.6/1.2

Indications for Use:
The UNIEXPERT 2 PLUS is a stationary general-purpose radiographic imaging system indicated for use in acquiring diagnostic X-Ray images of osseous structures and soft tissues of the human body to aid physicians with patient diagnosis. The system has analogue, computed radiography (CR) as well as digital radiography (DR) imaging capabilities. The UNIEXPERT 2 PLUS is not indicated for use in mammography.

Summary of Technological Characteristics Comparison to Predicate Device:
The UNIEXPERT 2 PLUS and the predicate device incorporate very similar technological characteristics and indications for use are essentially the same. They are comprised of a similar set of components with comparable construction and are configured essentially the same. The following table provides information for comparison of both systems.

Feature	UNIEXPERT 2 PLUS	Predicate Q-Rad Radiographic System	Comparison to Predicate
510(k) Number	K200944	K011486	
Indications For Use	The UNIEXPERT 2 PLUS iis a stationary general-purpose radiographic imaging system indicated for use in acquiring diagnostic X-Ray images of osseous structures and soft tissues of the human body to aid physicians with patient diagnosis. The system has analogue, computed radiography (CR) as well as digital radiography (DR) imaging capabilities. The UNIEXPERT 2 PLUS is not indicated for use in mammography.	The Q-Rad Radiographic System is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The Q-Rad System is not indicated for use in mammography.	Indications for use for the UNIEXPERT 2 PLUS are the same as the predicate.
X-Ray Generator	Input power: 3 Phase 380-480 VAC, Output power options: 40kW, 50kW, 65kW, 80kW and 100kW. All are manufactured by: Communications and Power Industries (CPI) Available Models: CMP200, CMP200 DR, Indico IQ	Input Power Choices - Three Phase 380-480 VAC, 208-240 Single Phase 208-240VAC, or Stored Energy for low input power applications. Output power ranging from 32 kW to 80 kW	Both the UNIEXPERT 2 PLUS and the predicate incorporate X-Ray Generator system options with essentially the same technological characteristics with the exception of a Stored Energy option available for the predicate.

Feature	UNIEXPERT 2 PLUS	Predicate Q-Rad Radiographic System	Comparison to Predicate
Tube Stand	Adani Model ADN114.13.00.000 Vertical Travel: 61.02”/1550mm Longitudinal Travel: 78.74”/1080mm Transverse Travel: 7.48”/190mm Rotational Capability: Yes	Model QS-550 Vertical Travel: 60.5”/1537mm Longitudinal Travel: 98”/2489mm Transverse Travel: 10”/254mm Rotational Capability: Yes	Both the UNIEXPERT 2 PLUS and the predicate incorporate a floor mounted vertical tube support structure with vertical, horizontal and transverse travel as well as rotational capability.
FDA Performance Standard	all applicable performance standards under 21 CFR 1020	all applicable performance standards under 21 CFR 1020	Both the UNIEXPERT 2 PLUS and the predicate comply with the same FDA Performance Standard
Wall Stand	Adani Model ADN114.14.00.000 Vertical Travel: 56.69”/1440mm	Model QW-420 Vertical Travel: 60.5”/1537mm	The UNIEXPERT 2 PLUS and the predicate provide wall stands with similar designs and range of motion capabilities for patient positioning.
Patient Table	Adani Model ADN114.11.00.000 Vertical Travel: 14.37”/365mm Longitudinal Travel: 42.52”/1080mm Transverse Travel: 9.84”/250mm	Model QT-750 Vertical Travel: 11.5”/292mm Longitudinal Travel: 30.5”/775mm Transverse Travel: 11.5”/292mm	The UNIEXPERT 2 PLUS and the predicate provide patient tables with similar adjustability and range of motion capabilities for patient transfer and positioning.
Detector	Varex PaxScan 4336W v4 Varex PaxScan 4343R v3 PerkinElmer XRpad2 4336 Vieworks FXRD-1417N	DRX Wireless Detector DRX Fixed Detector DRX 2530 Wireless Detector	Detectors used with the UNIEXPERT 2 PLUS and the predicate device incorporate comparable design and technology for diagnostic image acquisition and processing.

Feature	UNIEXPERT 2 PLUS	Predicate Q-Rad Radiographic System	Comparison to Predicate
Beam Limiting Device	Ralco R 225 Ralco R 302A	The same Manual or Automatic Collimators as well as others with equivalent design characteristics	Beam Limiting Devices available with the UNIEXPERT 2 PLUS are equivalent to those provided with the predicate device
X-Ray Tube	X-Ray Tube C352-RTM 78 HS F:0.6/1.2 X-Ray Tube C352-RTM 782 HS F:0.6/1.2	X-Ray Tubes ranging from 140kHu to 600 kHU	X-Ray tubes available with the UNIEXPERT 2 PLUS are equivalent in design and functionality to those provided with the predicate device
User Interface and Imaging Software	Automated Work Stations (AWS) and StudyWorks Control Software Complex For The Radiography Room System	Q-Rad - DRX/TechVision/QVision	The UNIEXPERT 2 PLUS and the predicate incorporate similar image acquisition and management software

Summary of Technological Characteristics of the UNIEXPERT 2 PLUS as compared to the Predicate Device:

The technological characteristics of the UNIEXPERT 2 PLUS present no significant differences with respect to overall design and intended use when compared to the predicate device. The UNIEXPERT 2 PLUS incorporates components similar to the predicate device, including; an X-Ray generator, vertical floor mounted tubestand, patient table, wall stand, analog, CR as well as digital image capability, a beam limiting device and an X-Ray tube. The fundamental scientific technology of the UNIEXPERT 2 PLUS is the same as the predicate device.

Non-Clinical and Clinical Testing:

Non-clinical testing included verification and validation testing and image evaluation have been performed for the UNIEXPERT 2 PLUS system. Sample clinical images covering a range of anatomical areas were provided to demonstrate the overall imaging capabilities of the device. Risk analysis was performed on the entire system. All devices not manufactured by Adani and subject to CDRH performance standards are certified to comply with the standard by their respective manufacturers.

No new or modified indications for use have been introduced by the UNIEXPERT 2 PLUS system. It has the same intended use and is technologically, the same as the predicate device. Therefore, it is the determination of Adani that non-clinical testing is sufficient and that clinical testing is not required to support a determination of substantial equivalence.

Summary of Performance and Safety Testing:
System performance testing including functional testing of all mechanical and electrical functions, imaging performance, safety and EMC testing of the UNIEXPERT 2 PLUS system was conducted in accordance with IEC 60601-1-2:2014, IEC 60601-1:2005/A1:2012, IEC 60601-1-3:2013, IEC 60601-1-6:2013, IEC 6234:2006 and IEC 60601-2-54:2015. Verification and validation, as well as acceptance testing were conducted to verify that all features of the UNIEXPERT 2 PLUS functioned as intended. Results confirmed all performance criteria were met satisfactorily and fell within pre-determined acceptance criteria. The output of the verification and validation process confirmed functionality and safety to be within acceptable limits.

Summary of Software Verification/Validation and Acceptance Testing:
The StudyWorks Software Complex enables operation of the UNIEXPERT 2 PLUS system by way of controlling the components and ensures control of the entire image acquisition cycle, starting from the input of the patient registration data to visualization of the acquired image and transfer to a PACS server or saving to CD or DVD. The StudyWorks Software Complex uses DICOM as the interface for external communication. Software/Firmware verification and validation, as well as acceptance testing were conducted to verify that all features of the StudyWorks Software Complex functioned as intended and that results fell within pre-determined acceptance criteria.
Risk analysis was performed to identify potential hazards, mitigate risks and evaluate acceptance criteria for residual risks. Since a latent design flaw in the software tool could result in a misdiagnosis or delayed medical assistance, thus potentially causing a minor injury to the patient or operator, the level of concern for this software has been determined to be “moderate”. A summary of Verification and validation activities was prepared in accordance with the FDA document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Substantial Equivalence Discussion:
Intended use and indications for use of the Adani UNIEXPERT 2 PLUS system and the predicate, Q-Rad Radiographic System are the same. Both the UNIEXPERT 2 PLUS and the predicate perform the same functions utilizing the same technology. They include components of comparable design with similar technological characteristics and a similar operator interface. Imaging procedures are conducted in a similar manor on both the Adani UNIEXPERT 2 PLUS and the predicate Q- Rad Rdiographic System.

Substatial Equivalence Conclusion:
The Adani UNIEXPERT 2 PLUS system does not introduce any new indications for use, nor does the use of the systems introduce any new potential safety or effectiveness concerns when compared to the predicate, Q-Rad Radiographic System. Therefore, Adani concludes that the UNIEXPERT 2 PLUS diagnostic X-Ray systems is substantially equivalent with the predicate device.