April 29, 2022

NanoRay Biotech Co., Ltd
% Alice Chen
Regulatory Affair
7F., No.91, Xinhu 1st Rd., Neihu Dist.
Taipei City, 114
TAIWAN

Re: K220271
Trade/Device Name: Hand Diagnostic Radiography Imaging System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: January 31, 2022
Received: January 31, 2022

Dear Alice Chen:

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
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)*
K220271

Device Name
Hand Diagnostic Radiography Imaging System

Indications for Use *(Describe)*
The product is intended as an X-Ray source for diagnosis. Operators of the Hand Diagnostic Radiography Imaging System are healthcare professionals familiar with and responsible for the X-Ray examinations being performed.

Indication for use – The device is stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of hands of adults and children.

Limitations for use – This device is not intended for general radiographic X-Ray examinations other than the indicated use, or for mammographic, bone density, fluoroscopy and angiography applications.

The major functions of the Hand Diagnostic Radiography Imaging System is including:

- Hand and Wrist radiography
- Hand PA, AP, Oblique, Lateral

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 of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990.
The assigned 510(k) number is K220271 .

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Date Prepared: October 1, 2021

Subjective Device Name and Classification

Product Name:	Hand Diagnostic Radiography Imaging System
Common Name:	Digital Diagnostic X-Ray System
Regulation Name:	Stationary X-Ray System
CFR Classification:	21 CFR 892.1680
Device Class:	II
Product Code:	KPR
Panel:	Radiology

Legally Marketed Predicate Device

Product Name:	DIAMOND-5A/6A/8A
510(k) #:	K202156
Clearance Date:	September 10, 2020
Common Name:	Digital Diagnostic X-Ray System
Regulation Name:	Stationary X-Ray System
Device Class:	II
Product Code:	KPR
Panel:	Radiology

Device Description:

The Hand Diagnostic Radiography Imaging System is a stationary digital diagnostic X-ray system designed to use in generating radiographic images of hands or wrist.

The Hand Diagnostic Radiography Imaging System consists of a system enclosure (with shielding to protect users from exposure to radiation); an X-ray module consists of the X-ray tube (consists of the X-ray tube, cooling fluid, electronics, and casing), generator, and beam limiter; a CCD camera assists the hand position; and the LCD which provides a imagine to make sure the hand on the right position.

The Hand Diagnostic Radiography Imaging System is designed to operate with a Flat Panel Digital X-ray Detector Model Yushan 1417C (K201528), manufactured by InnoCare Inc.

The intended operators of the Hand Diagnostic Radiography Imaging System are healthcare professionals familiar with and responsible for the X-ray examinations being performed.

To minimize electrical, mechanical, and radiation hazards, the Hand Diagnostic Radiography Imaging System adheres to recognized and established industry practices and standards.

Indications for Use:

The product is intended as an X-Ray source for diagnosis. Operators of the Hand Diagnostic Radiography Imaging System are healthcare professionals familiar with and responsible for the X-Ray examinations being performed.

Indication for use – The device is stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of hands of adults and children.

Limitations for use – This device is not intended for general radiographic X-Ray examinations other than the indicated use, or for mammographic, bone density, fluoroscopy and angiography applications.

Summary of the technological characteristics:

Hand Diagnostic Radiography Imaging System is functionally equivalent to the following predicate device: DIAMOND-5A/6A/8A (K202156) cleared September 10, 2020.

The following tables demonstrates the intended uses and technical characteristics of Hand Diagnostic Radiography Imaging System are substantially equivalent to the predicate devices.

Any differences between the subject device and the predicated device has no negative impact on safety or efficacy of the subject device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Functional Specification Comparison Table for the Hand Diagnostic Radiography Imaging System and DIAMOND-5A/6A/8A (K202156)：

Specification	Hand Diagnostic Radiography Imaging System (Subject)	DIAMOND-5A/6A/8A (K202156) (Predicate)	Comparison Result
Device class	II	II	Same
Classification	Mobile x-ray system, Class II; 21 CFR 892.1680	Mobile x-ray system, Class II; 21 CFR 892.1680	Same
Product code	KPR	KPR	Same
Indications for Use	The device is stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of hands or wrist.	The device is a stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of human anatomy.	Similar*
Intended users	X-ray Technicians trained to operate the system	X-ray Technicians trained to operate the system	Same
Physical Characteristics			
FPD Detector	The Hand Diagnostic Radiography Imaging System is designed to operate with a Flat Panel Digital X-ray Detector Model Yushan 1417C, manufactured by InnoCare Inc (K201528).	The DIAMOND-5A/6A/8A can user three previously cleared digital flat panel detectors are: 1. Fujifilm, DR-ID 1272SE/ DR-ID 1274SE cleared under K142003 2. Varex, PaxScan4343W cleared under K161459 3. i-Ray, Mano4343W cleared under K201043	Same
Active Imaging Area Size	27 cm X 32 cm	43 cm X 43 cm	Similar*
Image Transfer	Gb Ethernet or 802.11 WiFi	Gb Ethernet or 802.11 WiFi	Same
Data Standard	DICOM	DICOM	Same
X-Ray Source			
Energy Range	40 to 80 kV	40 to 150 kV	Same
Anode	Fixed anode	Rotating anode	Same
Tube Current	0.01 to 0.50 mA	10 to 640 mA	Different*
Exposure	0.005 to 0.250 mAs	0.1 to 500 mAs	Different*

Focal Spot Size	0.2 mm	0.6/1.2 mm	Similar*
Image Management Software			
Horizontal Flip	Available	Available	Same
Vertical Flip	Available	Available	Same
Rotate CW/CCW	Available	Available	Same
Text Annotation	Unavailable	Available	Different*
Ruler: Distance tool	Unavailable	Available	Different*
Angle measurement tool	Unavailable	Available	Different*
Zoom	Available	Available	Same
Magnify	Available	Available	Same
Image panning	Available	Available	Same
Auto fitting to window size	Available	Available	Same
Image crop/cut function	Available	Available	Same
Image copy	Unavailable	Available	Different*
Recover the original image	Unavailable	Available	Different*
Window level CD Burning	Unavailable	Available	Different*
DICOM Print	Unavailable	Available	Different*
Image Stitching	Unavailable	Available	Different*

*: The label will be explained in the executive summary.

Performance Data

Nonclinical Testing:

The Hand Diagnostic Radiography Imaging System, has been assessed and tested and has passed predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by the subject device and followed the process documented in the System Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Summary:

Based on the performance as documented in the V&V Testing, the subject device was found to have a safe and effectiveness profile that is similar to the predicate device.

V&V Testing Plan and Reports: The list is as follows

Test Plan and Reports
A15_Design Verification Proposal_Complete System Development
A16_Design Verification Proposal_Hardware Architecture Development
A17_Design Verification Proposal_Software development
A18_Design Verification Proposal_Production process development
A19_Design Verification Report_Hardware Architecture Development
A20_Design Verification Report_Software development
A21_Design Verification Proposal_Validation of I/O Back Board Assembly
A22_Design Verification Proposal_Validation of Distribution Board Assembly
A23_Design Verification Proposal_Validation of Mini Console Assembly
A24_Design Verification Proposal_Validation of the Assembly of the Light Strip Control Module
A25_Design Verification Proposal_Communication Test Validation of the Final Product
A26_Design Verification Proposal_Validation of the Functionality of the Final Product
A27_Product Engineering Test Report_Validation of I/O Back Board Assembly
A28_Product Engineering Test Report_Validation of Distribution Board Assembly
A29_Product Engineering Test Report_Validation of Mini Console Assembly

A30_Product Engineering Test Report_Validation of the Assembly of the Light Strip Control Module
A31_Product Engineering Test Report_Communication Test Validation of theFinal Product
A32_Product Engineering Test Report_Validation of the Functionality of the Final Product

The following International Standards were used to develop and verify the system. The Hand Diagnostic Radiography Imaging System, device has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

Std#	Safety/EMC Standards Description	FDA Rec. Standard#	Ann#
IEC 60601-1:2005/ A1:2012	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-4	A56
IEC 60601-1-2:2014 (Fourth Editiion)	Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic compatibility	19-8	A55
IEC 60601-1-3:2008 (second edition) + A1 2013	Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	12-269	A57
IEC 60601-2-28:2017	IEC 60601-2-28 Medical electrical equipment Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	12-309	A52
IEC 60601-2-54:2009 / A1:2015, A2:2018	IEC 60601-2-54 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	12-317	A58
IEC 62304: Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	13-79	A36-A48
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices	5-114	A62
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices	5-125	A3, A59-A61

The Hand Diagnostic Radiography Imaging System, device has followed all the guidance listed in the table:

Guidance	Document issued on
Pediatric Information for X-ray Imaging Device Premarket Notifications	November 28, 2017
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	May 11, 2005
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff	October 2, 2014
Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices Guidance for Industry and Food and Drug Administration Staff	July 11, 2016
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance for Industry and Food and Drug Administration Staff	September 14, 2018
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff	July 28, 2014
Applying Human Factors and Usability Engineering to Medical Devices	February 3, 2016
NEMA PS 3.1 - 3.20 (2016). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard.	June 27, 2016
Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	November 01, 2016

And labeling also includes reference to the Image Gently website (http://www.imagegently.org/).

Conclusion:

Based on comparison of indications for use, technological features, and performance testing result, the Hand Diagnostic Radiography Imaging System is found to be as safe and effective as the predicate device. It has been shown to be substantially equivalent to the predicate device.