Philips Healthcare (Suzhou) Co., Ltd.
℅ Ms. Mary Zhu
Senior Regulatory Engineer
No. 258, Zhong Yuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
REPUBLIC OF CHINA

July 9, 2020

Re: K201640
Trade/Device Name: DuraDiagnost
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: June 1, 2020
Received: June 16, 2020

Dear Ms. Zhu:

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)*
K201640

Device Name
DuraDiagnost

Indications for Use *(Describe)*
The DuraDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic 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) number: K201640

510(k) Summary

SPECIAL 510(k) Summary of Safety and Effectiveness

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

Date Prepared:	June 01, 2020	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, ZhongYuan Road, Suzhou Industrial Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Establishment Registration Number: 3009529630 2nd manufacturing site: Philips Medical Systems Nederland B.V. Veenpluis 6, 5684PC Best, The Netherlands Establishment Registration Number: 3003768277	
Contact Person:	Mary Zhu Senior Regulatory Engineer Phone: +86-021-24128746(cell: +86-183-5113-2881) Fax: +86-512-68018677 E-mail: Mary.ZHU@philips.com	
Device Name:	**DuraDiagnost**	
Classification:	Classification Name	Stationary X-Ray System
	Classification Regulation:	21CFR §892.1680
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary product code:	KPR (System, X-Ray, Stationary)
	Secondary code:	MQB(21 CFR 892.1680)
Predicate Device:	Trade Name:	DuraDiagnost
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K141381-June 12, 2014
	Classification Regulation:	21 CFR, Part 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code	KPR, MQB
Reference Device 1:	Trade Name:	MobileDiagnost WDR 2.2
	Manufacturer:	SEDECAL SA

	510(k) Clearance:	K191813- August 2, 2019
	Classification Regulation:	21CFR 892.1720
	Classification Name:	Mobile x-ray system
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code	IZL, MQB
Reference Device 2:	Trade Name:	Philips Eleva Workspot with SkyFlow
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K153318- December 22, 2015
	Classification Regulation:	21 CFR 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code	MQB, LLZ
Reference Device 3:	Trade Name:	DigitalDiagnost C90
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K182973- January 11, 2019
	Classification Regulation:	21CFR 892.1680
	Classification Name:	Stationary X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code	MQB, KPR, LLZ

Device description:

The **DuraDiagnost** is a flexible digital radiography (DR) system that is designed to provide fast and smooth radiography examinations of sitting, standing or lying patients.

The **DuraDiagnost** consist of the following components: Tube column with X-ray assembly, wall stand with detector carrier, patient table with detector carrier and floating table top, high voltage generator, and acquisition and reviewing workstation for post-processing, storage and viewing of images. Images may be transferred via a DICOM network for printing, storage and detailed review.

Indications for use:

The **DuraDiagnost** is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the

patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Fundamental scientific technology:

The fundamental scientific technology utilized in the **DuraDiagnost** and the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014) is equivalent with regards to the functionality of the following components: Integrated tube column, patient table with a floating table top, high-voltage generator, dual-focus rotation anode X-Ray tube, manual beam limiting device, digital detector, wall stand and workstation for images post-processing, storage and viewing (See Table 1 comparing the **DuraDiagnost** to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014) provided below).

The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the **DuraDiagnost** when compared to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014).

The wireless portable detector of the **DuraDiagnost** is identical to the wireless portable detector (SkyPlate E) of the currently marketed and reference device 1, MobileDiagnost WDR 2.2 (K191813- August 2, 2019) manufactured by SEDECAL SA. Therefore, both the wireless portable detector (Skyplate E) of the **DuraDiagnost** and the currently marketed and reference device 1, MobileDiagnost WDR 2.2 employ identical fundamental scientific technology.

The **DuraDiagnost** and the currently marketed and Reference Device 3, DigitalDiagnost C90 (K182973- January 11, 2019) manufactured by Philips Medical Systems DMC GmbH are provided with identical; fixed RAD detector (Pixium 4343RCE), UNIQUE 2 Post Processing software and embedded Windows 10 operating system. Therefore, **DuraDiagnost** and the currently marketed and reference

device 3, DigitalDiagnost C90 employ identical fundamental scientific technology.

Table 1 **Comparison of Technological Characteristics of Currently marketed and Predicate DuraDiagnost versus the DuraDiagnost**			
Feature	**Predicate Device: DuraDiagnost (K141381)**	**Device: DuraDiagnost**	**Comment**
Basic information			
Product Code	KPR & MQB	Identical	No difference; thus, demonstrating SE.
Regulation No.	21 CFR 892.1680	Identical	No difference; thus, demonstrating SE.
Device Class	II	Identical	No difference; thus, demonstrating SE.
Electrical Requirement	Input voltage: 3- phase, 200/208/240/380/400/415/440/480/500V ac; Frequency:50/60Hz; Current: Short term: 112A (with generator M-CABINET CXA Pro 50kW), 134A (with generator M-CABINET CXA Pro 65kW), 160A (with generator M-CABINET CXA Pro 80kW); Long term: 10A.	Input voltage: 3- phase, 200/208/240/380/400/415/440/480/500V ac; Frequency:50/60Hz; Current: Short term: 112A (with generator M-CABINET CXA Pro 50kW), 134A (with generator M-CABINET CXA Pro 65kW), Long term: 10A.	Equivalent. The **DuraDiagnost** and the currently marketed and predicate DuraDiagnost are both provided with similar electrical requirements. Therefore, no impact on the safety or effectiveness of the device. Thus, demonstrating SE.
Design characteristic			
X-ray Tube	RO 1750 ROT 360 & SRO 33100 ROT 360	Identical	No difference; thus, demonstrating SE.
Max Tube Voltage	150kV	Identical	No difference; thus, demonstrating SE.
Focal Spot Size	0.6mm/1.2mm	Identical	No difference; thus, demonstrating SE.
Tube Max power	50KW/100KW (250W equivalent anode input power)	Identical	No difference; thus, demonstrating SE.
Anode Type	Rotation	Identical	No difference; thus, demonstrating SE.

Generator	Philips Healthcare (Suzhou), M-CABINET CXA Pro 50kW, M-CABINET CXA Pro 65kW, M-CABINET CXA Pro 80kW	Philips Healthcare (Suzhou), M-CABINET CXA Pro 50kW, M-CABINET CXA Pro 65kW,	Equivalent. **DuraDiagnost** and the currently marketed and predicate DuraDiagnost are both provided with 50KW/65KW generators.Thus, demonstrating SE.
Max Power	50KW/65KW/80KW	50KW/65KW	
KV range	40-150	Identical	No difference; thus, demonstrating SE.
Milli ampere sec (mAs) product	0.4 mAs-600 mAs (with AEC control)	Identical	No difference; thus, demonstrating SE.
Collimator			
Operation Mode	Manual collimation	Identical	No difference; thus, demonstrating SE.
Shape of Beam	Rectangular	Identical	No difference; thus, demonstrating SE.
Detector			
Type	Digital Detector • Fixed RAD Detector • Wireless Static Detector	Identical	No difference; thus, Demonstrating SE.
Fixed RAD Detector	Pixium 4343RG	Pixium 4343RCE (Note: this detector is identical to fixed RAD detector of the currently marketed and Reference Device 3, DigitalDiagnost C90 cleared under K182973).	The difference between 4343RCE and 4343RG is scintillator material and other minor differences of image area and image matrix as compared in this table. The differences don't affect the safety or effectiveness. And the fixed RAD detector Pixium 4343RCE of the **DuraDiagnost** is identical to the fixed RAD detector of the currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019, Philips Medical Systems DMC). Thus, demonstrating SE
Wireless Static Detector	• SkyPlate Large (Trixell 3543EZ)	• SkyPlate Large (Trixell 3543EZ)	The SkyPlate Large Detector of the **DuraDiagnost** is identical to the SkyPlate

		• SkyPlate E (Trixell 3543DR) (Note: this detector is identical to the Skyplate E Detector of the currently marketed and reference device 1, MobileDiagnost WDR 2.2 cleared under K191813).	Large Detector of the currently marketed and Predicate DuraDiagnost **(**K141381, SkyPlate E is additionally added dectector. There are minor differences between SkyPlate E and the Skyplate Large detector of image area, image matrix and pixel size as compared in this table. The minor differences don't affect the safety or effectiveness. And the Skyplate E Detector of **DuraDiagnost** is identical to the Skyplate E Detector of the currently marketed and reference device 1, MobileDiagnost WDR 2.2 (K191813- August 2, 2019). Thus, demonstrating SE
X-ray Scintillator Material	• GdOS (Fixed: Pixium 4343RG)	• Cesium Iodide (Fixed: Pixium 4343RCE. Pixium 4343RCE is identical to fixed RAD detector of the currently marketed and Reference Device 3, DigitalDiagnost C90 cleared under K182973)	The fixed RAD detector of the **DuraDiagnost** and currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019, Philips Medical Systems DMC） are both fabricated from identical Cesium Iodide material , thus demonstrating SE. The Wireless detector of the **DuraDiagnost** and the currently marketed and predicate DuraDiagnost are both fabricated from identical Cesium Iodide material, thus demonstrating SE.
	• Cesium Iodide (Wireless: SkyPlate Large)	• Cesium Iodide (Wireless: SkyPlate Large and SkyPlate E)	
Image Area	• 42.5cm x 42.5cm (Fixed: Pixium 4343RG)	• 42.03cm x 42.54cm(Fixed: Pixium 4343RCE)	The image area of the **DuraDiagnost**, provided with fixed RAD detector is

	• 34.5cm x 42.1cm (Wireless: SkyPlate Large)	• 34.5cm x 42.1cm(Wireless: SkyPlate Large)	identical to the image area of the Fixed RAD Detector of the currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019, Philips Medical Systems DMC), thus demonstrating substantial equivalence The image area of the proposed **DuraDiagnost**, provided with wireless detector SkyPlate Large is identical to the wireless detector SkyPlate Large of the currently marketed and Predicate DuraDiagnost (K141381). Thus, demonstrating SE. The image area of the proposed Wireless Detector SkyPlate E is identical to the Wireless Detector SkyPlate E of the currently marketed and reference device 1, MobileDiagnost WDR 2.2 (K191813- August 2, 2019, Sedecal SA,). thus demonstrating SE
		• 34.5cm x 42.5cm(Wireless: SkyPlate E)	
Image Matrix	• 2,874 x 2,869 (Fixed: Pixium 4343RG)	• 2,874 x 2840 (Fixed: Pixium 4343RCE)	The image matrix of the proposed **DuraDiagnost** Philips Medical Systems DMC, provided with fixed RAD detector is identical to the image matrix of the
	• 2330 x 2846 (Wireless-SkyPlate Large)	• 2330 x 2846 (Wireless-SkyPlate Large)	

		• 2156 x 2653 (Wireless-SkyPlate E)	currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019,). thus demonstrating substantial equivalence. The image matrix of the **DuraDiagnost** provided with the wireless SkyPlate Large Detector is identical to the wireless SkyPlate Large of the currently marketed predicate Device DuraDiagnost, (K141381). Thus demonstrating SE. The image matrix of the **DuraDiagnost** provided with wireless detector SkyPlate E is similar to the currently marketed and Reference Device 1, MobileDiagnost WDR 2.2 (K191813- August 2, 2019, Sedecal SA). Infinitesimal change in the image size (X-ray field) does not impact clinical Image Quality. Therefore, they are equivalent and there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.

Pixel Size	• 148 µm (Fixed: Pixium 4343RG)	• 148 µm (Fixed: Pixium 4343RCE)	The pixel size of the proposed DuraDiagnost Philips Medical Systems DMC, provided with fixed RAD detector is identical to the pixel size of the currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019,). thus demonstrating substantial equivalence. The pixel size of the DuraDiagnost provided with the wireless SkyPlate Large Detector is identical to the wireless SkyPlate Large of the currently marketed predicate Device DuraDiagnost, (K141381). Thus demonstrating SE. The pixel size of the DuraDiagnost provided with wireless detector SkyPlate E is identical to the currently marketed and Reference Device 1, MobileDiagnost WDR 2.2 (K191813- August 2, 2019, Sedecal SA), thus demonstrating SE.
	• 148 µm(Wireless-SkyPlate Large)	• 148 µm(Wireless-SkyPlate Large)	
		• 160 µm (Wireless-SkyPlate E)	
Analog / Digital (A/D) conversion	16 bits	Identical	No difference; thus, demonstrating SE.
Table			
Table type	Fixed and Height adjustment	Height adjustment	The **DuraDiagnost** is provided with height adjustment table that is also provided with the currently marketed and predicate

			DuraDiagnost. Thus demonstrating SE.
Height adjustment	51.5 cm to 75.0 cm above floor, motorized adjustment	51.5 cm to 91.5 cm above floor, motorized adjustment	The height adjustment of the proposed DuraDiagnost, provided with height adjustable table is identical to the currently marketed and Reference Device 3, DigitalDiagnost C90(K182973- January 11, 2019, Philips Medical Systems DMC). thus, demonstrating SE.
Tabletop longitudinal travel range	+/- 550mm	Identical	No difference; thus, demonstrating SE.
Tabletop Lateral travel	+/- 130mm	Identical	No difference; thus, demonstrating SE.
Loading (patient weight)	210 Kg	Identical	No difference; thus, demonstrating SE.
Wall Stand			
Vertical movement range	1500mm	Identical	No difference; thus, demonstrating SE.
Movement mode	Manual	Identical	No difference; thus, demonstrating SE..
Tube Stand			
Type	Floor mounted	Identical	No difference; thus, demonstrating SE.
Tube rotation	+/- 120 degree	Identical	No difference; thus, demonstrating SE.
Longitudinal movement range	1400mm	Identical	No difference; thus, demonstrating SE.
Source to Image Distance（SID）			
SID	Table: 40-115cm; Wallstand: 110-245cm	Identical	No difference; thus, demonstrating SE.
External Connectivity			
DICOM	DICOM compatible	Identical	No difference; thus, demonstrating SE.
Software Platform			
Software	Eleva WorkSpot	Identical	No difference; thus, demonstrating SE.
SkyFlow Software	No	Yes	The **DuraDiagnost** includes the SkyFlow software that is also used in the currently marketed and Reference Device 3, Eleva Workspot with SkyFlow, (K153318- December 22, 2015, Philips Medical Systems DMC), thus, demonstrating SE.
Image Processing Algorithm	UNIQUE	UNIQUE 2	UNIQUE 2 image processing algorithm provided with **DuraDiagnost** ., was

			previously cleared with the currently marketed and Reference Device 3, DigitalDiagnost C90 (K182973- January 11, 2019, Philips Medical Systems DMC). Upgrading to UNIQUE2 image processing algorithm does not alter the clinical workflow, hence no impact on the safety or effectiveness of the device; thus, demonstrating SE
Operating System	Windows 7 embedded	Windows 10 embedded	Introduction of operating system Windows 10 embedded does not impact clinical image quality. Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.

Based on the information provided above, the **DuraDiagnost** is considered substantially equivalent to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014) in terms of fundamental scientific technology.

Summary of Non-Clinical Performance data:

This 510(k) premarket notification contains the technical documentation, which demonstrates that the **DuraDiagnost** is substantially equivalent to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014). The technical documentation includes non-clinical verification / validation tests. These tests were performed on the DuraDiagnost according to the following international and FDA-recognized consensus standards:

- International and FDA-recognized consensus standards:
  - AAMI / ANSI ES60601-1: 2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 (consolidated text) Medical electrical equipment –Part 1: General requirements for basic safety and essential performance. (Edition 3.1). FDA/CDRH recognition number 19-4.

- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances – Requirements and tests (Edition 4.0 2014). FDA/CDRH recognition number 19-8.
- IEC 60601-1-3, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment. (Edition 2.1 2013). FDA/CDRH recognition number 12-269.
- IEC60601-2-28 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis, (Edition 2.0 2010-03). FDA/CDRH recognition number 12-204.
- IEC 60601-2-54, Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy (Edition 1.1 2015). FDA/CDRH recognition number 12-296.
- IEC 60601-1-6, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability (Edition 3.1 2013). FDA/CDRH recognition number 5-89.
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1 2015) FDA/CDRH recognition number 13-79
- IEC 62366−1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.0 2015). FDA/CDRH recognition number 5-114.
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40.

- CFR 1020.30 Diagnostic x-ray systems and their major components.
- CFR 1020.31 Radiographic equipment.
- Device specific guidance document, entitled "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices – September 1, 2016"

- FDA's Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – May 11, 2005."
- FDA's Guidance document entitled, "Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" ,issued October 2, 2014
- Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 28, 2017

Non-clinical verification and validation tests have been performed with regards to the intended use, the technical claims, requirement specifications, and the risk management results.

Non-clinical verification and validation test results demonstrate that **DuraDiagnost***:*

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents.
- meets the acceptance criteria and is adequate for its intended use.

Therefore, **DuraDiagnost** is substantially equivalent to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014) in terms of safety and effectiveness.

Summary of Clinical Data:

The **DuraDiagnost** does not require clinical study since substantial equivalence to the primary currently marketed and predicate device was demonstrated with the following attributes:

- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

Furthermore, the SkyPlate E detector and Pixium 4343RCE detector utilizes the same design, technology and Image acquisition workflow compared to the previously Skyplate Large detector and Pixium 4343RG

detector used in the marketed and predicate DuraDiagnost (K141381, June 12, 2014). All technical detector characteristics that potentially have an influence on image quality are assessed and verified according to FDA Guidance for Industry and Food and Drug Administration Staff: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices; issued on September 1, 2016.

Substantial Equivalence Conclusion:

The **DuraDiagnost** is substantially equivalent to the currently marketed and predicate DuraDiagnost (K141381, June 12, 2014) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, ISO 14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-54, IEC 60601-1-6, IEC 60601-2-28, IEC 62304, and IEC 62366-1.

The results of these tests demonstrate that **DuraDiagnost** met the acceptance criteria and is adequate for its intended use.