Philips Medical Systems DMC GmbH
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

September 30, 2020

Re: K202564
Trade/Device Name: DigitalDiagnost C90
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, KPR, LLZ
Dated: September 2, 2020
Received: September 4, 2020

Dear Prithul Bom:

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

5. Statement of Indication for Use/Intended Use

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)*

K202564

Device Name

DigitalDiagnost C90

Indications for Use *(Describe)*

The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost C90 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and 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.

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K202564

6. 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:	September 23, 2020	
Manufacturer:	Philips Medical Systems DMC GmbH Röntgenstraße 24 22335 Hamburg, GERMANY Establishment registration number: 3003768251	
Contact Person:	Ming Xiao Regulatory Affairs Manager Phone: +49 40 34971-2306 Fax: +49 40 5078-2147 E-mail: ming.xiao@philips.com	
Device Name:	***DigitalDiagnost C90***	
Classification:	Trade Name:	DigitalDiagnost C90
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Regulation: Regulation Description:	21CFR 892.1680 Stationary x-ray system
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Classification Product Code:	MQB, KPR, LLZ
Predicate Device:	Trade Name:	DigitalDiagnost C90
	Manufacturer:	Philips Medical Systems DMC GmbH
	510(k) Clearance:	K182973- January 11, 2019
	Classification Regulation:	21CFR 892.1680
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Panel:	90 – Radiology
	Device Class:	Class II
	Product Code:	MQB, KPR, LLZ
Reference Device for SkyPlate E Detector:	Trade Name :	MobileDiagnost wDR 2.2
	Manufacturer:	Sedecal S.A
	510(K) Clearance:	K191813- August 2, 2019

Classification Regulation:	21CFR 892.1720
Classification Name:	Mobile X-ray Systems
Classification Panel:	90- Radiology
Device Class:	Class II
Product Code:	IZL, MQB

Device Description

The proposed ***DigitalDiagnost C90*** is same as the 510(K) approved predicate **(**K182973) as mentioned below

It is a high-end digital radiography system consisting of a height adjustable patient support table and a ceiling suspension consisting of a tube including a control handle used to acquire images with a flat panel fixed RAD detector. Additionally, different vertical stands for the radiography examinations are available. The ceiling suspension can be moved in longitudinal and lateral directions and additionally the tube can be tilted and rotated as well. The proposed ***DigitalDiagnost C90*** is configured with a Philips x-ray generator and a flat panel fixed RAD detector, Pixium 4343RCE, together with the tube these components form the radiography Image Chain.

The proposed ***DigitalDiagnost C90*** introduces a new wireless portable detector, pixium 3543DR i.e. SkyPlate E (cleared in reference device 510(K) K191813) and their relevant grids, in addition to the family of SkyPlate detectors (pixium 3543EZ i.e. Large and pixium 2430EZ i.e. Small) that are already integrated in the currently marketed (predicate) DigitalDiagnost C90 (K182973).

Indications for Use/Intended Use:

The Indication for Use of the proposed ***DigitalDiagnost C90*** is identical to that of the currently marketed and predicate device, DigtalDiagnost C90 (K182973- January 11, 2019) and is as follows:

The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost C90 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.

Fundamental Scientific Technology:

The proposed ***DigitalDiagnost C90*** employs the same basic construction and fundamental scientific technology as the currently marketed predicate DigtalDiagnost C90 (K182973, January 11, 2019), with regards to the functionality of all its components

The proposed ***DigitalDiagnost C90*** employs the same cleared features as predicate DigitalDiagnost C90 as follows

- fixed RAD detector (Pixium 4343RCE, K170113, February 9, 2017),
- wireless detectors (SkyPlate Detector, cleared by Eleva Workspot for DigitalDiagnost, K141736, July 25, 2014),
- image chain acquisition–station and workflow (Eleva Workspot with SkyFlow, K153318, December 22, 2015).

Only modification to the proposed is the introduction of SkyPlate E Detector and their relevant grids (Reference device, K191813- August 2, 2019). The additional SkyPlate E detector that has been integrated in the proposed ***DigitalDiagnost C90***, has equivalent design, technology and Image acquisition workflow compared to the previously cleared detector (SkyPlate Family detectors), used in the marketed predicate device DigtalDiagnost C90 (K182973, January 11, 2019), except difference in the pixel size. 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. Further the Non-clinical information sufficiently supports the substantial equivalence as per chapter VII- Non clinical Considerations of FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

The aforementioned modifications have also been evaluated in safety risk assessment report. The risks associated with these changes are considered in the risk management report and risk management activities show that all risks are sufficiently mitigated and that the overall residual risks are acceptable. The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the proposed ***DigitalDiagnost C90*** when compared to the currently marketed and predicate DigitalDiagnost C90.

Summary of technological characteristics:
The proposed ***DigitalDiagnost C90*** has same design, indications for use, fundamental scientific technology and similar technological characteristics as the marketed predicate device, DigitalDiagnost C90. Both devices are equivalent with respect to table features, Ceiling suspension CSM, Vertical stand feature. Both uses the same fixed RAD detector, Image chain acquisition station and workflow and Wireless detectors of SkyPlate family. The only modification in the proposed DigitalDiagnost C90 is the introduction of the SkyPlate E detector and its relevant grid. The modifications do not affect the clinical work flow or the clinical image quality demonstrating that the proposed DigitalDiagnost C90 is substantially equivalent to marketed predicate device, DigitalDiagnost C90 (K182973).
Table below provides comparison of the proposed DigitalDiagnost C90 with the predicate (marketed) DigitalDiagnost C90. It also includes the comparison of the SkyPlate E detector with the SkyPlate detector provided with the currently marketed and predicate DigitalDiagnost C90.

	Predicate Device: ***DigitalDiagnost C90 (K182973- January 11, 2019)***	***Proposed Device:*** ***DigitalDiagnost C90 (K202564)***	***Discussion & Conclusion***
Table Features			
Height adjustable table (TH-2)			

Height adjustment	51.5 cm to 91.5 cm above floor, motorized adjustment	Same	Equivalent; No impact to safety and effectiveness of the device.
Table weight	335 kg	Same	Equivalent; No impact to safety and effectiveness of the device.
Max. patient weight	• Static load center: 375 kg • Dynamic load center: 318 kg • Dynamic load off center: 210 kg	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top Type	Floating table top of sandwich design with Getalit overlay	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top Dimension	240 cm x 75 cm	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top travel	• longitudinal: ±56 cm • transverse: ±12.8 cm, electromagnetic brakes	Same	Equivalent; No impact to safety and effectiveness of the device.
Single side suspended table (TH-S)			
Height adjustment	51 cm to 91 cm motorized adjustment	Same	Equivalent; No impact to safety and effectiveness of the device.
Table weight	214 kg	Same	Equivalent; No impact to safety and effectiveness of the device.
Max. patient weight	• table top center: 225kg • end of table top: 135kg	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top Type	Floating table top of sandwich design with Kevlar overlay, flat top	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top Dimension	260 cm x 75 cm	Same	Equivalent; No impact to safety and effectiveness of the device.

Thickness of table top	4.7 cm	Same	Equivalent; No impact to safety and effectiveness of the device.
Table top travel	• longitudinal: ±20 cm, hydraulic brakes • transverse: ±20 cm, hydraulic brakes	Same	Equivalent; No impact to safety and effectiveness of the device.
Patient coverage with fixed RAD detector	• longitudinal: 208 cm • Transversal: 83 cm	Same	Equivalent; No impact to safety and effectiveness of the device.
Celling Suspension CSM			
Type	Four-part aluminum telescopic column with spring counter balanced holder for X-ray tube assembly; adaptable to individual room heights	Same	Equivalent; No impact to safety and effectiveness of the device.
Ceiling height at source image distance 110 cm	2.83 to 3.21 m	Same	Equivalent; No impact to the safety and effectiveness of the device.
Movement	3.26 m to 3.41m	Same	Equivalent; No impact to the safety and effectiveness of the device.
Transverse travel	1.49 m to 3.21 m	Same	Equivalent; No impact to the safety and effectiveness of the device.
Vertical travel	1.65 m	Same	Equivalent; No impact to safety and effectiveness of the device.
X-ray tube assembly rotation	• around vertical axis: 360° (±180°) with lock position every 45° • around horizontal axis: ±115°, lock	Same	Equivalent; No impact to safety and effectiveness of the device.

	positions 0° and ±90°		
Length of rails	4.3 m	Same	Equivalent; No impact to safety and effectiveness of the device.
Collimator	• Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible • With light field indicator • With 2 Lasers and Camera	Same	Equivalent; No impact to safety and effectiveness of the device.
Vertical Stand			
Vertical moveable stand (VM)			
Hardware	Counterbalanced rugged column for motorized vertical movement of the detector unit	Same	Equivalent; No impact to safety and effectiveness of the device.
Vertical travel	35 cm to 185 cm	Same	Equivalent; No impact to safety and effectiveness of the device.
Horizontal travel	• Motorized: 3.475 m • with extension rails, motorized: 5.5 m	Same	Equivalent; No impact to safety and effectiveness of the device.
Swiveling range	0° to 90° (right or left orientated execution)	Same	Equivalent; No impact to safety and effectiveness of the device.
Lock-in positions	manual or every 15°	Same	Equivalent; No impact to safety and effectiveness of the device.
Fixed Vertical Stand (VS)			
Hardware	Counterbalanced rugged column for motorized and manual vertical movement of the detector	Same	Equivalent; No impact to safety and effectiveness of the device.

Vertical travel	30 cm to 180 cm	Same	Equivalent; No impact to safety and effectiveness of the device.
Installation	Floor and wall attachment or floor only	Same	Equivalent; No impact to safety and effectiveness of the device.
Fixed RAD Detector	pixium 4343RCE	Same	Equivalent; No impact to safety and effectiveness of the device
Wireless Static Detector	• SkyPlate Small (pixium 2430EZ) • SkyPlate Large (pixium 3543EZ)	• SkyPlate Large (pixium 3543EZ) • SkyPlate Small (pixium 2430EZ) • SkyPlate E (pixium 3543DR)	Addition of SkyPlate E detector does not affect the clinical workflow or clinical image quality so there is no impact to the safety and effectiveness of the device.
Generator	High-voltage generator 65kW or 80kW	Same	Equivalent; No impact to safety and effectiveness of the device.
Tube	High power X-ray Tube, Philips SRO 33100	Same	Equivalent; No impact to safety and effectiveness of the device.
SkyFlow	Yes	Same	Equivalent; No impact to safety and effectiveness of the device.
Eleva Workspot	Yes	Same	Equivalent; No impact to safety and effectiveness of the device.
SkyPlate Detector Sharing	Yes	Same	Equivalent; No impact to safety and effectiveness of the device.
Automatic Image stitching	Yes	Same	Equivalent; No impact to safety and effectiveness of the device.
Detectors			
Type	Digital wireless flat detector	Same	Equivalent; No impact to safety and effectiveness of the device.
Detector Models	• SkyPlate Large (pixium 3543EZ) • SkyPlate Small (pixium 2430EZ)	• SkyPlate Large (pixium 3543EZ) • SkyPlate Small (pixium 2430EZ)	Addition of SkyPlate E detector does not affect the clinical workflow or clinical image quality so there is no

		• SkyPlate E (pixium 3543DR)	impact to the safety and effectiveness of the device.
X-Ray Absorber	CsI Scintillator	Same	Equivalent; No impact to safety and effectiveness of the device.
Installation type	Portable	Same	Equivalent; No impact to safety and effectiveness of the device.
Readout Mechanism	Thin Film Transistor	Same	Equivalent; No impact to safety and effectiveness of the device.
Detector Size	• SkyPlate Small: 328mm x 268mm x 16 mm • SkyPlate Large: 384mm x 460mm x 16 mm	• SkyPlate Small: Same • SkyPlate Large: same • SkyPlate E: 384.5 mm x 460.5 mm x 16.0 mm	Equivalent size does not affect the clinical workflow or clinical image quality so there is no impact to the safety and effectiveness of the device.
Maximum X-ray Dose for Linear Response	50 µGy	Same	Equivalent; No impact to safety and effectiveness of the device.
Maximum Usable Dose	• SkyPlate Small: 75 µGy • SkyPlate Large: 75 µGy	• SkyPlate Small: Same • SkyPlate Large: Same • SkyPlate E: 80 µGy	Equivalent or better; No impact to safety and effectiveness of the device.
Image Processing	Eleva Workstation	Same	Equivalent; No impact to safety and effectiveness of the device.
Maximum Lifetime Dose	100 Gy	Same	Equivalent; No impact to safety and effectiveness of the device.
Detector Weight	• SkyPlate Small: 1.6 Kg including battery • SkyPlate Large: 2.8 kg including battery	• SkyPlate Small: Same • SkyPlate Large detector: same • SkyPlate E: 3.1 kg including battery	It has no impact on clinical workflow. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE

Image Size (X-ray field)	• SkyPlate Small:284X222mm • SkyPlate Large: 344.8 mm x 421.2 mm	• SkyPlate Small: Same • SkyPlate Large: Same • SkyPlate E detector: 345 mm x 426 mm	This difference in the Image Size (X-ray field) does not impact clinical Image Quality. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Pixel Size	• SkyPlate Small & Large: 148 µm	• SkyPlate Small & Large: Same • SkyPlate E: 160 µm	The difference of 12 µm pixel size does not impact the image resolution to an extent that can impact the clinical image quality. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Image matrix size (Number of pixels)	• SkyPlate Small: 1500 X 1920 Pixels • SkyPlate Large: 2330 x 2846 pixels	• SkyPlate Small: same • SkyPlate Large: same • SkyPlate E: 2156 x 2662 pixels	Infinitesimal change in the image size (X-ray field) and reduction in number of pixels due to 160 µm pixel size does not impact clinical Image Quality. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Nyquist Frequency	• SkyPlate Small & large: 3.38 lp/mm	• SkyPlate Small & large: Same • SkyPlate E: 3.125 lp/mm	This difference in the Nyquist Frequency does not impact clinical Image Quality. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Modulation Transfer Function (MTF), typical values	• SkyPlate Small & Large 1 lp/mm 61% 2 lp/mm 30% 3 lp/mm 14% 3.38 lp/mm 10% (Nyquist)	• SkyPlate Small & large: Same • SkyPlate E: 1 lp/mm 62% 2 lp/mm 34% 3 lp/mm 18% 3.125 lp/mm 16% (Nyquist)	This difference in the Modulation Transfer Function does not impact clinical Image Quality. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Detective Quantum Efficiency (DQE),	• SkyPlate Small & large: DQE at 2.0 µGy	• SkyPlate Small & large: Same • SkyPlate E: DQE at 2.0 µGy	This difference in the Detective Quantum Efficiency does not impact clinical Image Quality.

typical values	Lp/mm % 0 70 1 51 2 42 3 29 3.38 19 (Nyquist)	Lp/mm % 0 70 1 51 2 42 3 22 3.125 18 (Nyquist)	Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
ADC Digitisation	16 Bit	Same	Equivalent; No impact to safety and effectiveness of the device.
Signal to Electronic Noise Ratio (SENR)	• SkyPlate Small & Large: Min 38 dB – typical: 43 dB (@ 1 µGy)	• SkyPlate Small & large: Same • SkyPlate E: Min 37 dB – typical: 42.8 dB (@ 1 µGy)	Equivalent; No impact to safety and effectiveness of the device.
Data Interface to Workstation	• AP to workspot: 1 GBit/s Ethernet • Detector Ethernet via BUC: 100 Mbit/s Ethernet • Detector to AP: 150 Mbit/s WLAN (gross transfer rate)	Same	Equivalent; No impact to safety and effectiveness of the device.
Grids			
Type	• Large Grids for SkyPlate Large (468 mm × 476 mm × 25 mm) • Small Grid for SkyPlate Small (280 mm × 354 mm × 25 mm)	• Large Grids for SkyPlate Large: Same • Small Grid for SkyPlate Small: Same • Large Grids for SkyPlate E (468 mm × 476 mm × 25 mm)	Addition of new grids for SkyPlate E introduction has no impact on clinical workflow. Therefore, no impact on safety and effectiveness of the device; thus, demonstrating SE
Indications for Use	The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital	Same	Equivalent; No impact to safety and effectiveness of the device.

	radiographic images. The DigitalDiagnost C90 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography		

Summary of Non-Clinical Performance Data:

This 510(k) premarket notification contains the technical documentation, which demonstrates that the proposed ***DigitalDiagnost C90*** is substantially equivalent to the currently marketed predicate DigitalDiagnost C90 (K182973, January 11, 2019). The technical documentation includes non-clinical verification / validation tests. These tests have been performed on the proposed ***DigitalDiagnost C90*** according to the following international and FDA-recognized consensus standards, as well as additional non-standard performance tests.

- IEC 60601-1, Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems
- IEC 60601-1-2, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- IEC 60601-1-3, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54, Medical electrical equipment. Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62220-1, Medical electrical equipment. Characteristics of digital X-ray imaging devices. Determination of the detective quantum efficiency
- IEC 62304, Medical device software. Software life-cycle processes
- IEC 60601-1-6, General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 14971, Medical devices. Application of risk management to medical devices

Additional non-standard performance tests have been performed to demonstrate the safety and effectiveness:

- System Verification Test
- Image Quality Test
- Human Factors and Usability Engineering Test

Non-Clinical performance testing confirmed the proposed ***DigitalDiagnost C90***:

- Complies with the aforementioned international and FDA-recognized consensus standards.
- Meets the acceptance criteria of the non-standard performance tests and is adequate for its intended use.

The results of testing support that the proposed ***DigitalDiagnost C90*** is substantially equivalent to the currently marketed and predicate device DigtalDiagnost C90 (K182973, January 11, 2019) in terms of safety and effectiveness.

Summary of Clinical Data:

The proposed ***DigitalDiagnost C90*** did not require clinical study since substantial equivalence to the currently marketed and predicate device was demonstrated with the following attributes:

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

Substantial Equivalence Conclusion:

The proposed ***DigitalDiagnost C90*** is substantially equivalent to the currently marketed predicate device DigtalDiagnost C90 (K182973, January 11, 2019) 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, IEC 62304, IEC 62366 and ISO 14971. The results of these tests demonstrate that proposed ***DigitalDiagnost C90*** met the acceptance criteria and is adequate for this intended use.