Philips Medical Systems DMC GmbH
Ming Xiao
Regulatory Affairs Manager
Roentgenstrasse 24
Hamburg, 22335 DE
GERMANY

January 11, 2019

Re: K182973
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: October 23, 2018
Received: October 26, 2018

Dear Ming Xiao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182973

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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PHILIPS

7. 510(k) Summary

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:	revised January 09, 2019	
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 5078-2425 E-mail: ming.xiao@philips.com	
Device Name:	***DigitalDiagnost C90***	
Classification:	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: Secondary Product Codes:	MQB KPR, LLZ
Predicate Device:	Trade Name:	Philips Eleva Workspot for DigitalDiagnost
	Manufacturer:	Philips Medical System DMC
	510(k) Clearance:	K141736 – July 25, 2014
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code: Subsequent Product Code:	MQB KPR

Reference Device_1 (primary device):	Trade Name:	Philips Bucky Vision
	Manufacturer:	Philips Medical System DMC
	510(k) Clearance:	K982795 – November 24, 1998
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code: Subsequent Product Code:	MQB KPR
Reference Device_2:	Trade Name:	Eleva Workspot with SkyFlow
	Manufacturer:	Philips Medical System DMC
	510(k) Clearance:	K153318 – December 22, 2015
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code: Subsequent Product Code:	MQB LLZ
Reference Device_3:	Trade Name:	Pixium 4343RCE
	Manufacturer:	Philips Medical System DMC
	510(k) Clearance:	K170113 – February 9, 2017
	Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Regulation:	21CFR 892.1680
	Classification Panel:	90 -- Radiology
	Device Class:	Class II
	Product code:	MQB

Device Description:

The *DigitalDiagnost C90* 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 *DigitalDiagnost C90* is configured with a Philips x-ray generator and a flat panel fixed RAD detector, Pixium 4343RCE (K170113 – February 9, 2017), together with the tube these components form the radiography Image Chain. As additional options, a portable detector (K141736 – July 25, 2014) can be used for free exposures as well as in the patient support table or in the vertical stand.

The proposed *DigitalDiagnost C90* is considered substantially equivalent to the currently marketed and predicate device, Philips Eleva Workspot for DigitalDiagnost (K141736, July 25, 2014), previously designated with primary product code MQB and subsequent product code LLZ, in terms of indications for use and design characteristics. Nevertheless product code KPR –being also considered substantially equivalent- (based upon submission Philips Bucky Vision (K982795, November 24, 1998) is chosen for this new submission, because it refers back to a complete "stationary x-ray system".

The proposed *DigitalDiagnost C90* incorporates the following features, previously cleared by FDA in the following reference devices:

Design Feature/ Attribute	**Currently Marketed and Reference Device - Philips Medical Systems**
Primary device	Philips Bucky Vision (K982795, November 24, 1998)
Image Chain acquisition–station and workflow (Eleva Workspot)	Eleva Workspot with SkyFlow (K153318, December 22, 2015)
Fixed static detector	Pixium RCE (K170113, February 9, 2017)

The Indications for Use for the proposed *DigitalDiagnost C90* are 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.

Device History / Predicate Device for *DigitalDiagnost C90*:

510(k)	Decision Date	Cleared Device	Product Code	Predicate Device	Intended Use	Release Product
K982795	24.11.1998	Philips Bucky Vision	MQB, KPR	K945278	The Philips BuckyVision is intended for use in general radio-graphic exam-inations and applications wherever con-ventional screen-film system may be used (excluding fluoroscopy, angiography and mammo-graphy).	DigitalDiagnost Release 1 (issued as Bucky Vision for cleared 510(k) declaration K982795 in 1998)
K063781	05.01.2007	Philips XD-S Direct Radiography Workstation/Package	LLZ, MQB	K982795	As part of a radiographic system, the Philips XD-S is intended to acquire, process, store, display and export digital radiographic images. The Philips XD-S is suitable for all routine radio-graphy exams, including specialist areas like intensive care, trauma, or pediatric work, excluding mammography.	DigitalDiagnost Release 2
K090625	24.03.2009	Wireless Portable Detector FD-W17	MQB	K982795 K063781	As part of a radiographic system, the Wireless Portable Detector FD-W17 is intended to acquire digital radio-graphic images. The Wireless Portable	DigitalDiagnost Release 3

510(k)	Decision Date	Cleared Device	Product Code	Predicate Device	Intended Use	Release Product
					Detector FD-W17 is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammo-graphy.	
K131483	07.10.2013	Philips Pixium 4343RC	MQB	K982795 K063781 K090625	As part of a radiographic system, the Philips Pixium 4343RC is intended to acquire digital radiographic images. The Philips Pixium 4343RC is suitable for all routine radio-graphy exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammography.	DigitalDiagnost Release 4
K141736	25.07.2014	Philips Eleva Workspot for DigitalDiag nost	MQB, LLZ	K090625	As part of a radiographic system, the Philips Eleva Workspot with SkyPlate Detectors is intended to acquire, process, store, display and export digital radiographic	DigitalDiagnost Release 4 with SkyPlate Detectors

510(k)	Decision Date	Cleared Device	Product Code	Predicate Device	Intended Use	Release Product
					images. The Philips Eleva Workspot with SkyPlate Detectors is suitable for all routine radio-graphy exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angiography and mammo-graphy.	
K18xxxx		DigitalDiag nost C90	MQB, LLZ, KPR	K141736	The *Digital-Diagnost C90* is intended to acquire, process, store, display and export digital radio-graphic images. The *Digital-Diagnost C90* is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammo-graphy	*DigitalDiagnost C90*

Fundamental Scientific Technology:

The *DigitalDiagnost C90* employs the same basic construction and fundamental scientific technology as the currently marketed and predicate Philips Eleva Workspot for DigitalDiagnost (K141736, July 25, 2014), with regards to the functionality of the following components: table, system-control, X-Ray tube, detector, and generator etc. (see the comparison table comparing

the *DigitalDiagnost C90* to the currently marketed and predicate Philips Eleva Workspot for DigitalDiagnost provided below).

The *DigitalDiagnost C90* employs the following cleared features: fixed RAD detector (Pixium 4343RCE, K170113, February 9, 2017), wireless detectors (SkyPlate Detector, cleared by Eleva Workspot for DigitalDiagnost, K141736, July 25, 2014)) and the image chain acquisition–station and workflow (Eleva Workspot with SkyFlow, K153318, December 22, 2015). The fixed detector, wireless portable detectors, and the image chain and workstation of the *DigitalDiagnost C90* are identical to the fixed detector, wireless portable detectors, and the image chain and workstation of the currently marketed and reference devices. Therefore, the fixed detector, wireless portable detectors, and the image chain and workstation employ identical fundamental scientific technology.

The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the *DigitalDiagnost C90* when compared to the currently marketed and predicate Philips Eleva Workspot for DigitalDiagnost.

- **Summary of technological characteristics:**

The *DigitalDiagnost C90* has similar indications for use and technological characteristics as the predicate device, Philips Eleva Workspot for DigitalDiagnost. Comparisons of the technological characteristics demonstrate the substantial equivalence to the predicate device.

	Predicate Device: Philips Eleva Workspot for DigitalDiagnost Release 4 with SkyPlate Detectors / (K141736)	***Proposed Device: DigitalDiagnost C90 (K18xxxx)***	***Discussion & Conclusion***
Table Features			
Height adjustable table (TH)			
Height adjustment	51.5 cm to 91.5 cm above floor, motorized adjustment	51.5 cm to 91.5 cm above floor, motorized adjustment	Equivalent; No impact to safety or effectiveness of the device.
Table weight	335 kg	335 kg	Equivalent; No impact to safety or effectiveness of the device.
Max. patient weight	Static load center: 375 kg Dynamic load center: 318 kg Dynamic load off center: 210 kg	Static load center: 375 kg Dynamic load center: 318 kg Dynamic load off center: 210 kg	Equivalent; No impact to safety or effectiveness of the device.
Table top Type	Floating table top of sandwich design with Getalit overlay	Floating table top of sandwich design with Getalit overlay	Equivalent; No impact to safety or effectiveness of the device.
Table top Dimension	240 cm x 75 cm	240 cm x 75 cm	Equivalent; No impact to safety or effectiveness of the device.
Table top travel	• longitudinal: ±60 cm • transverse: ±13 cm, electromagnetic brakes	• longitudinal: ±60 cm • transverse: ±12 cm, electromagnetic brakes	Similar: Minor differences in the table top travel does not affect the safety or effectiveness of the device.
Single side suspended table (TH-S)			
Height adjustment	50.3 cm to 90.3 cm motorized adjustment	50.3 cm to 90.3 cm motorized adjustment	Equivalent; No impact to safety or effectiveness of the device.
Table weight	214 kg	214 kg	Equivalent; No impact to safety or effectiveness of the device.
Max. patient weight	225 kg	•table top center: 225 kg •end of table top: 135 kg	Equivalent; No impact to safety or effectiveness of the device.
Table top Type	Floating table top of sandwich design with Kevlar overlay, flat top	Floating table top of sandwich design with Kevlar overlay, flat top	Equivalent; No impact to safety or effectiveness of the device.

	Predicate Device: Philips Eleva Workspot for DigitalDiagnost Release 4 with SkyPlate Detectors / (K141736)	***Proposed Device: DigitalDiagnost C90 (K18xxxx)***	***Discussion & Conclusion***
Table top Dimension	260 cm x 75 cm	260 cm x 75 cm	Equivalent; No impact to safety or effectiveness of the device.
Thickness of table top	4.7 cm	4.7 cm	Equivalent; No impact to safety or effectiveness of the device.
Table top travel	• longitudinal: ±20 cm, hydraulic brakes • transverse: ±20 cm, hydraulic brakes	• longitudinal: ±20 cm, hydraulic brakes • transverse: ±20 cm, hydraulic brakes	Equivalent; No impact to safety or effectiveness of the device.
Patient coverage with fixed RAD detector	• longitudinal: 208 cm • Transversal: 83 cm	• longitudinal: 208 cm • Transversal: 83 cm	Equivalent; No impact to safety or 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	Four-part aluminum telescopic column with spring counter balanced holder for X-ray tube assembly; adaptable to individual room heights	Equivalent; No impact to safety or effectiveness of the device.
Ceiling height at source image distance 110 cm	2.83 m to 3.21 m	2.65 m to 3.20 m	Similar: Minor differences in the Ceiling height does not affect the safety or effectiveness of the device.
Movement	3.28 m to 3.44 m	3.28 m to 3.44 m	Equivalent; No impact to safety or effectiveness of the device.
Transverse travel	1.50 m to 3.22 m	1.49 m to 3.21 m	Similar: Minor differences in the Transverse travel do not affect the safety or effectiveness of the device.
Vertical travel	1.65 m	1.65 m	Equivalent; No impact to safety or effectiveness of the device.
X-ray tube assembly rotation	• around vertical axis: 360° (±180°) with lock position every 45° • around horizontal axis: ±125°, lock positions 0° and ±90°	• around vertical axis: 360° (±180°) with lock position every 45° • around horizontal axis: ±125°, lock positions 0° and ±90°	Equivalent; No impact to safety or effectiveness of the device.

	Predicate Device: Philips Eleva Workspot for DigitalDiagnost Release 4 with SkyPlate Detectors / (K141736)	***Proposed Device: DigitalDiagnost C90 (K18xxxx)***	***Discussion & Conclusion***
Length of rails	4.3 m	4.3 m	Equivalent; No impact to safety or effectiveness of the device.
Collimator	• Ralco P 225 ACS DHHS • Motorized automatic collimation • Manual overrule possible • With light field indicator	• Ralco P 225 ACS DHHS • Motorized auto-matic collimation • Manual overrule possible • With light field indicator • With 2 Lasers and Camera	Ralco Collimator R225 ACS is cleared by Ralco K091517 (on 14, July 2009), Ralco P 225 ACS DHHS is cleared by Letter to File on 02, February 2016 based on K091517. Laser and Camera are already certified and cleared as options in K091517. Equivalent; No impact to safety or effectiveness of the device.
Vertical Stand			
Vertical moveable stand (VM)			
Hardware	Counterbalanced rugged column for motorized vertical movement of the detector unit	Counterbalanced rugged column for motorized vertical movement of the detector unit	Equivalent; No impact to safety or effectiveness of the device.
Vertical travel	35 cm to 185 cm	35 cm to 185 cm	Equivalent; No impact to safety or effectiveness of the device.
Horizontal travel	• Motorized: 3.475 m • non-motorized: 3.71 m • with extension rails, motorized: 5.5 m • with extension rails, non-motorized: 5.5 m	• Motorized: 3.475 m • with extension rails, motorized: 5.5 m	Equivalent; No impact to safety or effectiveness of the device.
Swiveling range	0° to 90° (right or left orientated execution)	0° to 90° (right or left orientated execution)	Equivalent; No impact to safety or effectiveness of the device.
Lock-in positions	manual or every 15°	manual or every 15°	Equivalent; No impact to safety or effectiveness of the device.
Fixed Vertical Stand (VS)			
Hardware	Counterbalanced rugged column for motorized and manual vertical movement of the detector	Counterbalanced rugged column for motorized and manual vertical movement of the detector	Equivalent; No impact to safety or effectiveness of the device.
Vertical travel	30 cm to 180 cm	30 cm to 180 cm	Equivalent; No impact to safety or effectiveness of the device.

	Predicate Device: Philips Eleva Workspot for DigitalDiagnost Release 4 with SkyPlate Detectors / (K141736)	***Proposed Device: DigitalDiagnost C90 (K18xxxx)***	***Discussion & Conclusion***
Installation	Floor and wall attachment or floor only	Floor and wall attachment or floor only	Equivalent; No impact to safety or effectiveness of the device.
Fixed RAD Detector	Pixium 4343RC	Pixium 4343RCE	The proposed *DigitalDiagnost C90* includes the fixed RAD detector Pixium 4343RCE used in the currently marketed and reference device, Pixium 4343 RCE (K170113). Therefore, there is no impact on the safety or effectiveness of the device.
Wireless Static Detector	SkyPlate Detector family	SkyPlate Detector family	Equivalent; No impact to safety or effectiveness of the device.
Generator	High-voltage generator 65kW or 80kW	High-voltage generator 65kW or 80kW	Equivalent; No impact to safety or effectiveness of the device.
Tube	High power X-ray Tube, Philips SRO 33100	High power X-ray Tube, Philips SRO 33100	Equivalent; No impact to safety or effectiveness of the device.
SkyFlow	No	Yes	The proposed *DigitalDiagnost C90* includes the SkyFlow used in the currently marketed and reference device Eleva Workspot with SkyFlow, (K153318). Therefore, there is no impact on the safety or effectiveness of the device.
Eleva Workspot	Yes	Yes	Equivalent; No impact to safety or effectiveness of the device.
SkyPlate Detector Sharing	Yes	Yes	Equivalent; No impact to safety or effectiveness of the device.
Automatic Image stitching	Yes	Yes	Equivalent; No impact to safety or effectiveness of the device.
Indications for Use	As part of a radiographic system, the Philips Eleva Workspot with SkyPlate Detectors is intended to acquire, process, store, display and export	The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radio-graphic images. The	Equivalent; The Indications for Use for the proposed *DigitalDiagnost C90* is more general in nature and exactly the same as the currently marketed and

	Predicate Device: Philips Eleva Workspot for DigitalDiagnost Release 4 with SkyPlate Detectors / (K141736)	***Proposed Device: DigitalDiagnost C90 (K18xxxx)***	***Discussion & Conclusion***
	digital radiographic images. The Philips Eleva Workspot with SkyPlate Detectors is suitable for all routine radiography exams, including specialist areas like intensive care, trauma, or pediatric work, excluding fluoroscopy, angio-graphy & mammography.	DigitalDiagnost C90 is suitable for all routine radiography exam-inations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.	reference device, Philips Eleva Workspot for DigitalDiagnost (K141736).

Based on the information provided above, the *DigitalDiagnost C90* is considered substantially equivalent to the currently marketed and predicate device, Philips Eleva Workspot for DigitalDiagnost (K141736, July 25, 2014) in terms of fundamental scientific technology.

Summary of Non-Clinical Data:

This 510(k) premarket notification contains technical documentation which includes non-clinical verification and validation tests as well as image quality testing. Tests were performed on the proposed *DigitalDiagnost C90* according to the following international and FDA-recognized consensus standards:

- ISO 14971, Medical devices. Application of risk management to medical devices
- 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
- Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices, issued

September 1, 2016

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005
- Pediatric Information for X-ray Imaging Device Premarket Notifications, Draft, issued May 10, 2012
- Guidance for the Submission of Premarket Notifications for Medical Image Management Device, issued July 27, 2000

The test results demonstrate that the proposed *DigitalDiagnost C90* meets the acceptance criteria and is adequate for its intended use.

Based upon the same intended use, similar technology, software functionalities, same product configuration and administration, and similarity of materials, it can be concluded the proposed *DigitalDiagnost C90* is substantially equivalent to the predicate device, Philips EasyDiagnost Eleva, in terms of intended use, design characteristics, and safety and effectiveness.

The subject device DigitalDiagnost C90 is a combination of cleared Philips devices (Eleva Workspot, Bucky Vision, Pixium 4343RCE). Testing for integration of devices into a fully-functional system has been successfully performed.

Summary of Clinical Data:

The proposed *DigitalDiagnost C90* did not require a 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 including validation; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The comparison of technological characteristics, non-clinical performance data, safety testing, software validation, and clinical image concurrence data demonstrates that the device is as safe and effective as the predicate device. Philips Medical Systems concludes that the proposed *DigitalDiagnost C90* is substantially equivalent to the legally marketed predicate device, Philips Eleva Workspot for DigitalDiagnost.