Philips Medical Systems DMC GmbH
% Ming Xiao
Regulatory Affairs Manager North America
Roentgenstrasse 24-26
22335 Hamburg
GERMANY

February 5, 2018

Re: K173433
Trade/Device Name: ProxiDiagnost N90
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: November 9, 2017
Received: November 13, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 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)*
K173433

Device Name

ProxiDiagnost N90

Indications for Use *(Describe)*

ProxiDiagnost N90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding 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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# 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:** January 29, 2018

**Manufacturer:**
Philips Medical Systems DMC GmbH
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22335 Hamburg
GERMANY
Establishment registration number: 3003768251

**Contact Person:**
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**Device Name:** ***ProxiDiagnost N90***

| | | |
|---|---|---|
| **Classification:** | Classification Name: | Image-intensified fluoroscopic x-ray system |
| | Classification Regulation: | 21CFR 892.1650 |
| | Classification Panel: | 90 -- Radiology |
| | Device Class: | Class II |
| | Classification Product Code: | OWB |
| | Secondary Product Codes: | JAA |
| **Predicate Device:** | Trade Name: | Philips EasyDiagnost Eleva |
| | Manufacturer: | Philips Medical System DMC |
| | 510(k) Clearance: | K031535 – June 17, 2003 |
| | Classification Name: | Image-intensified fluoroscopic x-ray system; Stationary x-ray system; Spot-film device; Tilting Radiographic table |
| | Classification Regulation: | 21CFR 892.1650 |
| | Classification Panel: | 90 -- Radiology |

| | | |
|---|---|---|
| | Device Class: | Class II |
| | Product code: | JAA |
| **Reference Device_1:** | Trade Name: | CombiDiagnost R90 |
| | Manufacturer: | Philips Medical System DMC |
| | 510(k) Clearance: | K163210 – Jan 31, 2017 |
| | Classification Name: | Image-intensified fluoroscopic x-ray system |
| | Classification Regulation: | 21CFR 892.1650 |
| | Classification Panel: | 90 -- Radiology |
| | Device Class: | Class II |
| | Product code:<br>Secondary Product Codes: | JAA<br>KPR, MQB |
| **Reference Device_2:** | Trade Name: | Eleva Workspot with SkyFlow |
| | Manufacturer: | Philips Medical System DMC |
| | 510(k) Clearance: | K153318 – Dec 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:<br>Secondary Product Codes: | MQB<br>LLZ |
| **Reference Device_3:** | Trade Name: | Pixium 4343RCE |
| | Manufacturer: | Philips Medical System DMC |
| | 510(k) Clearance: | K170113 – Feb 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 |
| **Reference** | Trade Name: | SkyPlate Detector For Philips |

**Device_4:** Radiography/Fluoroscopy Systems

| | |
|---|---|
| Manufacturer: | Philips Medical System DMC |
| 510(k) Clearance: | K171461 – July 7, 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 *ProxiDiagnost N90* is a multi-functional nearby controlled fluoroscopy system in combination with a high-end digital radiography system consisting of a floor-mounted tilt-adjustable patient support table and a scan unit consisting of a tube and a flat panel dynamic detector, Pixium FE4343F, for the fluoroscopy examinations. The tabletop can be moved by a motor in the lateral and longitudinal direction and can be tilted -85° to +90° degrees. The scan unit tilts with the table and can be moved in the longitudinal and lateral direction, relative to the table and to the patient. The fully integrated system is provided with a x-ray tube(s) with collimator and high resolution displays. The *ProxiDiagnost N90* is configured with a Philips x-ray generator and a flat panel dynamic detector, Pixium FE4343F, components of the Philips radiography/fluoroscopy Image Chain. As additional options, the *ProxiDiagnost N90* can be used as a digital radiography system consisting of a mounted tube in a ceiling suspension together with the portable or fixed detector in the vertical stand.

The *ProxiDiagnost N90* uses the same workflow as the currently marketed and predicate device, Philips EasyDiagnost Eleva (K031535, cleared June 17, 2003). The *ProxiDiagnost N90* incorporates the following features, previously cleared by FDA in the following reference devices:

| **Design Feature/ Attribute** | **Currently Marketed and Reference Device** Philips Medical Systems |
|---|---|
| Image Chain acquisition–station and workflow (Eleva Workspot) | Eleva Workspot with SkyFlow (K153318, December 22, 2015) |
| Dynamic flat detector, PixiumFE4343F and motorized collimator (in ceiling suspensions) | CombiDiagnost R90 (K163210, January 31, 2017) |
| Wireless portable detector | SkyPlate Detector for Radiography/Fluoroscopy Systems (K171461, July 7, 2017) |
| Fixed static detector | Pixium 4343 RCE (K170113, February 9, 2017) |

**Indications for Use:**

*ProxiDiagnost N90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.*

**Fundamental Scientific Technology:**

The *ProxiDiagnost N90* employs the same basic construction and fundamental scientific technology as the currently marketed and predicate EasyDiagnost Eleva (K031533), with regards to the functionality of the following components: table, system-control, X-Ray tube, and generator (see the comparison table comparing the *ProxiDiagnost N90* to the currently marketed and predicate EasyDiagnost Eleva provided below).

The *ProxiDiagnost N90* employs the following cleared features: fixed detector (Pixium FE 4343F K163210), wireless detectors (Pixium 4343RCE, K170113, February 9, 2017; SkyPlate Detector for R/F Systems, K171461, July 7, 2017) and the image chain acquisition–station and workflow (fluoroscopy) (Eleva Workspot with SkyFlow, K153318, Dec 22, 2015). The fixed detector, wireless portable detectors, and the image chain and workstation of the *ProxiDiagnost N90* 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 *ProxiDiagnost N90* when compared to the currently marketed and predicate EasyDiagnost Eleva.

**Summary of technological characteristics:**

The *ProxiDiagnost N90* has similar indications for use and technological characteristics as the predicate device, EasyDiagnost Eleva. Comparisons of the technological characteristics demonstrate the substantial equivalence to the predicate device.

| | ***Primary Predicate Device: EasyDiagnost Eleva (K031535)*** | ***Proposed Device: ProxiDiagnost R90 (K173433)*** | ***Discussion*** |
|---|---|---|---|
| **Table Features** | | | |
| Working height (table top center to floorplate) | 83cm | 83.3cm | Similar; the range of working height does not affect the safety or effectiveness of the device. |
| Table tilt movement | -20° to +90°<br>Optional:<br>-30° to +90°<br>-45° to +90°<br>-85° to +90° | -90° to +90°<br>movement speed with variable 1 to 6°/s | Similar: The table tilt movement does not affect the safety or effectiveness of the device. |
| Table top suspension | Two sides suspensions | Two sides suspensions | Equivalent; No impact to safety or effectiveness of the device. |
| Table top | Plastic laminate or carbon | Sandwich of laminate, | Similar: The table top |

| | ***Primary Predicate Device: EasyDiagnost Eleva (K031535)*** | ***Proposed Device: ProxiDiagnost R90 (K173433)*** | ***Discussion*** |
|---|---|---|---|
| material | fiber | carbon and foam | material movement does not affect the safety or effective-ness of the device. |
| Table top movement | Lateral: -10 cm to + 9 cm<br>Longitudinal: ± 83 cm | Lateral: -10 cm to + 9 cm<br>Longitudinal: ± 83.5 cm | Equivalent; No impact to safety or effectiveness of the device. |
| Table top absorption | 0.7mm typical (@ 100kV, 2.7mm Al HVL) | 0.6mm Al typical @ 100kV | Similar: Minor differences in the table top absorption does not affect the safety or effectiveness of the device. |
| Maximum patient weight | 180 kg | static: 300 kg<br>tilt: 250 kg<br>all movements: 185 kg | The proposed *ProxiDiagnost N90* is able to hold more patient weight; this does not affect the safety or effective-ness of the device. |
| Lateral scan distance | 22 cm | 22 cm | Equivalent; No impact to safety or effectiveness of the device. |
| Lateral scan speed | Manual Movement | Manual Movement | Equivalent; No impact to safety or effectiveness of the device. |
| Longitudinal scan distance | 75 cm mechanical range | 75 cm mechanical range | Equivalent; No impact to safety or effectiveness of the device. |
| Table column angulation | -85° to +90° | -85° to +90° | Equivalent; No impact to safety or effectiveness of the device. |
| Source image distance | 73 cm – 103 cm,<br>88 cm – 118 cm with Geomat in extended position | 81 cm – 130 cm | Similar: The source image distance provided with the proposed *ProxiDiagnost N90* does not affect the safety or effectiveness of the device. |
| Collimator | Square / rectangular plus Iris | rectangular collimation | The rectangular collimator provided with the proposed *ProxiDiagnost N90* does not affect the safety or effectiveness of the device. It is the same collimator used in the currently marketed and reference device, CombiDiagnost R90 (K163210) |
| Grid | Parkable | Parkable | Equivalent; No impact to safety or effectiveness of the device. |
| Picture archiving and communication system | Yes | Yes | Equivalent; No impact to safety or effectiveness of the device. |
| Image chain (fluoroscopy) | Philips Image Intensifier / CCD TV / Digital Imaging | Philips Dynamic Eleva Image Chain | The proposed *ProxiDiagnost N90* includes the currently marketed and reference device, Eleva WorkSpot, |

| | ***Primary Predicate Device: EasyDiagnost Eleva (K031535)*** | ***Proposed Device: ProxiDiagnost R90 (K173433)*** | ***Discussion*** |
|---|---|---|---|
| | | | (K153318) as part of the image chain. In addition, this same image chain is used in the currently marketed and reference device, CombiDiagnost R90 (K163210). Therefore, there is no impact on the safety or effectiveness of the device. |
| Detector | Image Intensifier 23 cm, 31 cm or 38 cm | Pixium FE 4343F | The proposed *ProxiDiagnost N90* includes the fixed detector Pixium FE 4343F used in the currently marketed and reference device, CombiDiagnost R90 (K163210). Therefore, there is no impact on the safety or effectiveness of the device. |
| Modulation Transfer Function (MTF) (according to IEC 62220-1-3 standard) | Not available | lp/mm %<br>1 66<br>2 35<br>3 19<br>3.4 15 | The proposed *ProxiDiagnost N90* includes the fixed detector Pixium FE 4343F used in the currently marketed and reference device, CombiDiagnost R90 (K163210). Therefore, there is no impact on the safety or effectiveness of the device. |
| Detective Quantum Efficiency (DQE) (according to IEC 62220-1-3 standard) | Not available | DQE at 1 µGy<br>lp/mm %<br>0.05 65<br>1 51<br>2 41<br>3 27<br>3.4 18 | The proposed *ProxiDiagnost N90* includes the fixed detector Pixium FE 4343F used in the currently marketed and reference device, CombiDiagnost R90 (K163210). Therefore, there is no impact on the safety or effectiveness of the device. |
| Wireless Static Detector for Radiographic Exams | Wireless Portable Detector Pixium4600 (previous version of SkyPlate Detector) | SkyPlate Detector | The proposed *ProxiDiagnost N90* includes the currently marketed and reference device, SkyPlate Detectors for R/F Systems (K171461). Therefore, there is no impact on the safety or effectiveness of the device. |
| Wireless Static Detector for Radiographic Exams | N/A | Pixium RCE | The proposed *ProxiDiagnost N90* includes the currently marketed and reference device, Pixium RCE (K170113). Therefore, there is no impact on the safety or effectiveness of the device. |
| Generator | Philips Velara GCF/RF, 50kW, 65kW or 80kW | Philips Velara GCF/RF, 65 kW, optional 80 kW | Equivalent; No impact to safety or effectiveness of the |

| | ***Primary Predicate Device: EasyDiagnost Eleva (K031535)*** | ***Proposed Device: ProxiDiagnost R90 (K173433)*** | ***Discussion*** |
|---|---|---|---|
| | | | device. |
| Tube | Philips SRO 2550 or SRM 2250 GS | Philips SRM 2250 ROT-GS 504 or<br>SRO 2550 ROT380 or<br>SRO 33100 ROT380 (optional in CSM) | Equivalent; No impact to safety or effectiveness of the device. |
| System Control | Near by | Nearby | Equivalent; No impact to safety or effectiveness of the device. |
| Indications for Use | The Philips EasyDiagnost Eleva intended use is for the following applications: As a multi-functional/ universal system, general R/F, Fluoro-scopy, Radiography and Angiography can be performed along with pediatric examinations and some more specialized interventional applications. | *ProxiDiagnost N90* is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography. | Equivalent; The Indications for Use for the proposed *ProxiDiagnost N90* is more general in nature and exactly the same as the currently marketed and reference device, CombiDiagnost R90 (K163210). |

Based on the information provided above, the *ProxiDiagnost N90* is considered substantially equivalent to the currently marketed and predicate device, EasyDiagnost Eleva (K031535, June 17, 2003) 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 *ProxiDiagnost N90* 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
- 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
- Guidance for Radio Frequency Wireless Technology in Medical Devices, issued August 14, 2013
- Guidance for Management of Cybersecurity in Medical Devices, issued October 2, 2014

The test results demonstrate that the proposed *ProxiDiagnost N90* 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 *ProxiDiagnost N90* is substantially equivalent to the predicate device, Philips EasyDiagnost Eleva, in terms of intended use, design characteristics, and safety and effectiveness.

**Summary of Clinical Data:**

The proposed *ProxiDiagnost N90* 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 *ProxiDiagnost N90* is substantially equivalent to the legally marketed predicate device, EasyDiagnost Eleva.