October 1, 2021

Philips Medical Systems Nederland BV
% Swapnil Sharadkumar Jain, Ph.D.
Regulatory Affairs Specialist
Veenpluis 4-6
Best, 5684PC
THE NETHERLANDS

Re: K212813
Trade/Device Name: Zenition 70
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: August 27, 2021
Received: September 3, 2021

Dear Dr. Jain:

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,

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)*
K212813

Device Name
Zenition 70

Indications for Use *(Describe)*
The proposed Zenition 70 is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device.

The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

Applications:
- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

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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K212813 510(k) Summary

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

Date Prepared: **August 27, 2021**

Manufacturer:
Philips Medical Systems Nederland BV
Veenpluis 4-6, 5684 PC Best,
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Establishment Registration Number: 3003768277

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Device:	Trade Name:	**Zenition 70**
	Classification Name:	Image intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB, OXO, JAA
Predicate Device:	Trade Name:	*Zenition 70*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K183040 (December 6, 2018)
	Classification Name:	Image intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB, OXO, JAA
Reference Device:	Trade Name:	Digiscan FDX
	Manufacturer:	Allengers Medical Systems Limited
	510(k) Clearance:	K200218 (July 13, 2020)
	Classification Name:	Image intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB, OXO, JAA

Device description: The proposed **Zenition 70** is a mobile, diagnostic X-ray imaging and viewing system. It is designed for medical use in healthcare facilities where X-ray imaging is needed. The system comprises two main components: The C-arm stand and a mobile view station

Indications for Use: The proposed **Zenition 70** is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device.

The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

Applications:

- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

The proposed **Zenition 70** has identical indications to the currently marketed and predicate device Zenition 70. Based on the information provided above, the proposed **Zenition 70** is considered substantially equivalent to the currently marketed and predicate device Zenition 70 (K183040, December 6, 2018) in terms of Indications for Use.

Technological characteristics: The proposed **Zenition 70** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate Zenition 70.

The difference between the proposed **Zenition 70** and the predicate device Zenition 70 (K183040, December 6, 2018) is summarized as follows:

The Philips Medical Systems Nederland BV, Zenition 70 (K183040, December 6, 2018) device currently incorporates FD12 (Pixium 2121CV/S) and FD15 (Pixium 2630Sv) solid-state flat-panel detectors (FPD). This submission adds an additional option of a slightly larger FD17 (Pixium3030S) solid-state flat-panel detector and its associated Beam limiting device FD17 and Grid FD17. The newly introduced FD17 (Pixium3030S) detector has the same design, technology and image acquisition workflow compared to the previously cleared FD12 (Pixium 2121CV/S) and FD15 (Pixium 2630Sv) detectors used in the marketed predicate device Zenition 70 (K183040, December 6, 2018), except for difference in the dimensions. FD17 (Pixium3030S) detector is also manufactured by the same manufacturer of the already cleared FD12 (Pixium 2121CV/S) and FD15 (Pixium 2630Sv) detectors (Thales from France) used in the predicate device.

The differences between the proposed **Zenition 70** and the predicate device Zenition 70 (K183040, December 6, 2018) do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, the proposed **Zenition 70** is considered substantially equivalent to the

currently marketed predicate Zenition 70 in terms of fundamental scientific technology.

See Table 5-1 below comparing the proposed **Zenition 70** and the predicate device Zenition 70 (K183040, December 6, 2018). The outcome of this comparison demonstrates that the differences in the technological characteristics do not affect the safety or effectiveness of the proposed **Zenition 70** when compared to the currently marketed and predicate Zenition 70 (K183040, December 6, 2018).

The newly introduced FD17 (Pixium3030S) detector of the proposed **Zenition 70** is identical to the detector used in the currently marketed and reference device, Digiscan FDX (K200218, July 13, 2020) manufactured by Allengers Medical Systems Limited. Therefore, both the FD17 (Pixium3030S) detector of the proposed **Zenition 70** and the currently marketed and reference device, Digiscan FDX employ identical fundamental scientific technology.

Table 5-1. Technological characteristics comparison of the proposed Zenition 70 and the predicate device Zenition 70 (K183040, December 6, 2018)

Component /feature	Currently marketed and predicate device Zenition 70 (K183040, December 6, 2018)	Proposed Zenition 70	Comparison
X-ray Generator	iXion HF Generator Model: 10359400	iXion HF Generator Model: 10359400	No difference; thus, demonstrating SE.
X-ray tube	Model: RTM 780 H (Type RO- 0306)	Model: RTM 780 H (Type RO-0306)	No difference; thus, demonstrating SE.
X-ray tube housing assembly	iXion Monoblock V with X-ray tube RO-0306	iXion Monoblock V with X-ray tube RO-0306	No difference; thus, demonstrating SE.
Detectors (Image detection subsystem)	FD15 Flat detector (Pixium 2630Sv)	FD15 Flat detector (Pixium 2630Sv)	No difference; thus, demonstrating SE.
	FD12 Flat detector (Pixium 2121CV/S)	FD12 Flat detector (Pixium 2121CV/S)	No difference; thus, demonstrating SE.
	N/A	FD17 Flat detector (Pixium 3030S)	The optional FD17 (PX3030S) detector is based on the same design, scientific technology, and image acquisition workflow as the FD15 (PX2630Sv) and FD12 (PX2121CV/S) detectors used in the predicate device. The FD17 (PX3030S) is different compared to the FD15 (PX2630Sv) and FD12 (PX2121CV/S) detectors in dimensions

Component /feature	Currently marketed and predicate device Zenition 70 (K183040, December 6, 2018)	Proposed Zenition 70	Comparison
			and pixel size. There is no change in clinically relevant characteristics of the detector that relate to the acquisition to X-ray images and X-ray dose sensitivity. The image quality performance of the FD17 (PX3030S) and FD15 (PX2630Sv) and FD12 (PX2121CV/S) detector is compared and found to be equal**.** The change does not introduce new risks, and it was shown to be compliant with the international and FDA recognized standards IEC60601-1, IEC60601-2-43 and IEC60601-2-54 for basic safety and essential performance. 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". The optional FD17 (Pixium3030S) detector is already used in the currently marketed and reference device, Digiscan FDX (K200218, July 13, 2020). Hence, this change does not impact the safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Detachable grids	Grid FD15	Grid FD15	No difference; thus, demonstrating SE.
	Grid FD12	Grid FD12	No difference; thus, demonstrating SE.
	N/A	Grid FD17	The FD17 (PX3030S) detector introduction includes the introduction of a removable anti- scatter grid. The FD17 (PX3030S) detector grid has exactly same design and technology compared to FD15 (PX2630Sv) and FD12 (PX2121CV/S) grid used in currently marketed predicate device, except for the difference in dimensions. Addition of new grid for FD17 (PX3030S) introduction has no impact on clinical workflow. This change does not affect safety or effectiveness of the device. Thus,

Component /feature	Currently marketed and predicate device Zenition 70 (K183040, December 6, 2018)	Proposed Zenition 70	Comparison
			demonstrating substantial equivalence.
Collimator (Beam limiting device)	Beam limiting device FD15- PX2630Sv	Beam limiting device FD15- PX2630Sv	No difference; thus, demonstrating SE.
	Beam limiting device FD12- PX2121CV/S	Beam limiting device FD12 - PX2121CV/ S	No difference; thus, demonstrating SE.
	N/A	Beam limiting device FD17- Pixium3030 S	A new collimator for the FD17 - Pixium3030S has been designed such that it reuses the design of the existing predicate device, FD15 (PX2630Sv) and FD12 (PX2121S) collimator with the only exception the square fixed diaphragm that has a larger window to match the larger detector format of the FD17 - Pixium3030S. All other parts of the collimator are identical. Addition of new collimator for FD17 (PX3030S) introduction has no impact on clinical workflow. Hence, this does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Detector laser aiming device	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2)	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2)	No difference; thus, demonstrating SE.
Mobile C- arm Stand	Veradius R3.1 Stand with FD	Veradius R3.1 Stand with FD	No difference; thus, demonstrating SE.
Mobile Viewing Station	MVS BV Family R3	MVS BV Family R3	No difference; thus, demonstrating SE.
DICOM connectivity	DICOM compatible	DICOM compatible	No difference; thus, demonstrating SE.

Component /feature	Currently marketed and predicate device Zenition 70 (K183040, December 6, 2018)	Proposed Zenition 70	Comparison
Operating System	Windows 7 embedded	Windows 10 embedded	No change in software architecture as this is migration in same family of operating system. There are no changes in the Windows 10 operating system that influences the architecture of the application. Hence the overall architecture has remained the same during the process of migration. 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.
Touch screen monitor (TSM)	Touch screen monitor (TSM) option not available	Touch screen monitor (TSM) option available	The TSM replicates the same information as on the C-arm stand touchscreen enabling table side control of the C-arm stand functions. This is additional user interface on table side with no change in control mechanism, operating principle, or energy type. Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.
iApp (Interventional applications) software interface	iApp software interface option not available	iApp software interface option available	iApp is an optional feature that enables the proposed Zenition 70 to work with compatible third-party software medical devices/iApps. The third-party software application(s) will only do post processing functions, without impacting Zenition 70 operation workflow or intended use. This change in software only introduces non-therapeutic and non-diagnostic feature. Therefore, there is no impact on the safety and effectiveness of the device; thus, demonstrating SE.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed **Zenition 70** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents:

- ES60601-1:2005/(R)2012 and A1:2012 (Edition 3.1); Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Recognition Number: 19-4)
- IEC 60601-1-2 (Edition 4.0 2014-02); Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests (Recognition Number: 19-8)
- IEC 60601-1-3 (Edition 2.1 2013-04); Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment (Recognition Number: 12-269)
- IEC 60601-1-6 (Edition 3.1 2013-10); Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability (Recognition Number: 5-89)
- IEC 60601-2-43 (Edition 2.1 2017-05); Medical Electrical Equipment - Part 2-43: Particular Requirements For The Safety And Essential Performance Of X-Ray Equipment For Interventional Procedures (Recognition Number: 12-308)
- IEC 60601-2-54 (Edition 1.2 2018-06); Medical Electrical Equipment - Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment For Radiography And Radioscopy (Recognition Number: 12-317)
- IEC 60601-2-28 (Edition 2.0 2010-03); Medical Electrical Equipment - Part 2-28: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Tube Assemblies For Medical Diagnosis (Recognition Number: 12-204)
- IEC 62304 (Edition 1.1 2015-06); Medical device software – Software life cycle processes (Recognition Number: 13-79)
- IEC 62366-1 (Edition 1.0 2015-02); Medical devices – Part 1: Application of usability engineering to medical devices (Recognition Number: 5-114)
- ISO 14971 (Edition 2.0 2007-03); Medical Devices - Application Of Risk Management To Medical Devices (Recognition Number: 5-40)
- ISO 15223-1 (Edition 3.0 2016-11); Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied (Recognition Number: 5-117)
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff (Issue date: 9/1/2016)
- Pediatric Information for X-ray Imaging Device Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff (Issue date: 11/28/2017)

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff (Issue date: 5/11/2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (Issue date: 10/02/2014)

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.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the proposed **Zenition 70**:

- Complies with the above-mentioned international and FDA-recognized consensus standards and FDA guidance documents, and
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the proposed **Zenition 70** is substantially equivalent to the currently marketed Zenition 70 in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed **Zenition 70** did not require clinical study since substantial equivalence to the currently marketed and predicate device Zenition 70 was demonstrated with the following attributes:

- Indications for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Furthermore, the optional FD17 detector (Pixium3030S) utilizes the same design, technology and Image acquisition workflow compared to the previously FD12 (Pixium 212lCV/S) and FD15 (Pixium 2630SV) detectors used in the marketed and predicate device Zenition 70 (K183040, December 6, 2018). 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. The optional FD17 (Pixium3030S) detector is already used in the currently marketed and reference device, Digiscan FDX (K200218, July 13, 2020).