Philips Medical Systems Nederland BV
Sumit Kumar
Regulatory Approbation Officer
Veenpluis 4-6
Best, 5684PC
THE NETHERLANDS

December 6, 2018

Re: K183040
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: October 29, 2018
Received: November 1, 2018

Dear Sumit Kumar:

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

4 Indication for Use Statement

The Indication for Use Statement is included in the next pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183040

Device Name
Zenition 70

Indications for Use *(Describe)*

The **Zenition 70** device 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510 (k) Summary

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

Date Prepared: October 29, 2018

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

Primary Contact Person:
Sumit Kumar
Regulatory Approbation Officer
Phone: +91 7028039288
E-mail: sumit.kumar_3@philips.com

Secondary Contact Person:
Sonavane, Neena Sandeep
Regulatory Affairs Manager
Phone: +91 8446020023
E-mail: neena.sonavane@philips.com

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
Primary Product Code:	OWB
Secondary Product Code:	OXO, JAA

Primary Predicate Device:

Trade Name:	Veradius Unity
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K142708
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 Philips **Zenition 70** has identical indications to the currently marketed and predicate device Veradius Unity

Technological characteristics: The proposed **Zenition 70** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate Veradius Unity. The technology used in the development of the major components of the proposed **Zenition 70,** which includes X-ray generator, X-ray tube, X-ray tube housing assembly, Image detection system and beam-limiting device is identical to the currently marketed and predicate Veradius Unity. Modifications implemented in the proposed **Zenition 70** include

- Improved system architecture with PC platform.
- Monoblock reduced height and reduced filtration
- Introduction of an optional 12”(PX2121S) Flat Detector
- Live DVD recording option no longer supported
- System service functions
- Introduction of metal exclusion
- Improved DICOM connectivity workflow
- Introduction of the security features
- Improved User Interfaces
- Improved tube heat management
- Analogue video out no longer supported
- Room interface
- Audible signals

These above changes are 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 differences between the **Zenition 70** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, the **Zenition 70** is considered substantially equivalent to the currently marketed predicate *Veradius Unity* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

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

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015). FDA/CDRH recognition number 13-79.
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007). FDA/CDRH recognition number 5-40.
- IEC 60601-2-43 - Particular requirements for the safety of X-Ray equipment for interventional procedures (Edition 2.1, 2017). FDA/CDRH recognition number 12-308.
- IEC 60601-2-54, Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy (Edition 1.1 2015). FDA/CDRH recognition number 12-296.
- IEC 60601-2-28-Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (Edition 2.0 2010) FDA/CDRH recognition number 12-204.
- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.1). FDA/CDRH recognition number 19-4.
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests (Edition 4.0 2014). FDA/CDRH recognition number 19-8.
- IEC 60601-1-3, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance.-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment. (Edition 2.1 2013). FDA/CDRH recognition number 12-269.
- IEC 60601-1-6, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability (Edition 3.1 2013). FDA/CDRH recognition number 5-89.
- IEC 62366 IEC Application of Usability Engineering to Medical Devices (Edition 1.0 2015). FDA/CDRH recognition number 5-114
- 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 (document number 644)
- Pediatric information for x-ray imaging device premarket notifications (document number 1771)
- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337).
- Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices(document number (1757)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and FDA Staff (document number 1825).

- Radio frequency wireless technology in medical devices- Guidance for Industry and Food and Drug Administration Staff (document number 1618).

Non-clinical validation testing has been performed to cover the intended use, commercial claims, service needs, user needs, effectiveness of safety measures, instructions for use, and usability testing with representative intended users.

Non-clinical verification and validation test results demonstrate that the **Zenition 70**:

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

Summary of Clinical Performance Data:

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

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

Furthermore, the optional 12-inch detector in **Zenition 70** also has same design, technology and Image acquisition workflow compared to the previously cleared detector used in the marketed predicate device Veradius Unity, except difference in the dimension and 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. So Nonclinical information used to support the substantial equivalence as per FDA Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices.

Substantial Equivalence Conclusion:

The **Zenition 70** is substantially equivalent to the currently marketed predicate device *Veradius Unity K142708* in terms of indications for use, fundamental scientific technology and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that **Zenition 70** complies with the requirements specified in the international and FDA-recognized consensus standards and guidance, and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.