December 31, 2018

Philips Medical Systems Nederland BV
Sumit Kumar
Regulatory Approbation Officer
Veenpluis 4-6
BEST, NL 5684PC

Re: K183101
Trade/Device Name: Zenition 50
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: November 1, 2018
Received: November 7, 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,

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

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

510(k) Number *(if known)*

K183101

Device Name
Zenition 50

Indications for Use *(Describe)*

The Zenition 50 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.

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510(k) Summary

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

Date Prepared: November 1, 2018

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

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Device:	Trade Name:	**Zenition 50**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Primary Product Code:	OWB
	Secondary Product Code:	JAA, OXO
Primary Predicate Device:	Trade Name:	BV Pulsera
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K010435
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code:	OWB; JAA; OXO
Reference 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:	90-Radiology
Device Class:	Class II
Product Code:	OWB; JAA; OXO

Device description: The proposed **Zenition 50** 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 of two main components: the C-arm stand and a Mobile View Station(MVS)

Indications for Use: The proposed **Zenition 50** 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

Fundamental Scientific Technology: The proposed **Zenition 50** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate BV Pulsera. The technology used in the development of the major components of the proposed **Zenition 50**, which includes X-ray generator, X-ray tube housing assembly, and Image detection system is identical to the currently marketed and predicate BV Pulsera. See the below table for the comparison of the major components of the proposed **Zenition 50** and the currently marketed and predicate BV Pulsera.

The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the **Zenition 50** when compared to the currently marketed and predicate BV Pulsera.

Technological characteristics comparison of the currently marketed predicate device, BV Pulsera versus the proposed Zenition 50			
Component /feature	**Currently market BV Pulsera**	**Proposed Zenition 50**	**Conclusion**
X-ray Generator	iXion HF Generator Model : 10359400	iXion HF Generator Model : 10359400	Identical.
X-ray tube	Model: RTM 780 H (Type RO-0306)	Model :RTM 780 H (Type RO-0306)	Identical.

X-ray housing assembly	iXion Monoblock IV with X-ray tube RO-0306	iXion Monoblock V with X-ray tube RO-0306	Similar with minor change in monoblock design for providing more clearance to the floor. The monoblock design has been updated to reduce the height with 3.5cm, and thus improves clearance between the tank and the floor which resulting in more space to move. In addition, the filtration has been reduced to lower the amount of power necessary for the same dose. The updated monoblock is evaluated in risk management. The change does not introduce new risks. This change 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. Hence, this change does not impact the safety and effectiveness of the Device. Thus, demonstrating substantial equivalence.
Image Intensifier 9”	23HRC	23HRC	Identical.
Image Intensifier 12”	31GG	31GG	Identical
II Laser alignment tool	Z-LAD 9 Inch Z-LAD 12 Inch	Z-LAD 9 Inch Z-LAD 12 Inch	Identical
Beam Limiting Device	CoRa 9890 010 23201	Collimator IITV 459801200241	A new collimator has been designed such that it reuses the design of existing reference device *Veradius Unity* (K142708) FD15 (PX2630Sv) collimator with the only exception the square fixed diaphragm is removed to match the format for IITV9” and IITV12”. There is no change in the functional specification compared to predicate device. All other parts of the collimator are identical. This change 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. Hence, this does not impact safety or effectiveness of the device Thus, demonstrating substantially equivalent.
Laser Alignment tool	Tube Laser Aiming Device	Tube Laser Aiming Device	Changed to fit in new collimator. Functional specification are similar compared to predicate device. This tube laser unit is reused from the reference device Veradius Unity (K142708). Hence, this change do not impact the safety or effectiveness of the Device. Thus, demonstrating substantial equivalence
Mobile C-arm Stand	BV Pulsera Stand	Pulsera R3.1 Stand	The mechanical interfaces have been updated for the updated monoblock and the stand touchscreen. These changes are assessed in risk management, and they did not introduce new risks. The changes was also shown to be compliant with the FDA recognized standard IEC60601-1 for basic safety and essential performance. Therefore, the change does not impact safety and effectiveness. Thus, demonstrating substantial equivalence.
Mobile Viewing Station	MVS BV Family R2	MVS BV Family R3	The MVS has been changed to match the updated interfaces from the System architecture and room interface changes. These changes are assessed in risk management, and they did not introduce new risks. The changes was also shown to be compliant with the FDA recognized standard IEC60601-1 for basic safety and essential performance. Therefore, the change does not impact safety and effectiveness. Thus, demonstrating substantial equivalence
System architecture	Current System architecture	Improved system architecture with PC platform • Solved obsolescence in computing	These changes were assessed in risk management, and they did not introduce new risks. This change was shown to be compliant with the international and FDA recognized

		hardware and software by moving to state of the art computing hardware and corresponding interconnects. • Migrated system software to the new computing hardware • Migrated image processing from hardware to software implementation • Integrated internal distributed components related to power functions into the mains control unit to simplify the design • Integrated wireless network connection design to simplify configuration and setting to work by service engineers	standards IEC60601-1, IEC60601-2-43 and IEC60601-2-54 for basic safety and essential performance, IEC60601-1-2 for Electromagnetic compatibility, IEC62366 for application of usability engineering and the FDA Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21 CFR 1020.30 / 1020.32). Image processing performance is compared by means of an image quality performance comparison with the predicate device and found equal or improved, see **Appendix A38.** This change does not affect safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
ClearGuide and color coding	Not Present	Introduction of ClearGuide and color coding	These visual aids are ease-of-use improvements and improve communication in the OR between surgeon and operator. These features are reused from the reference device *Veradius Unity* (K142708). The changes do not introduce new risks or change any of the existing risks compared to the predicate device. This change does not affect safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
C-arm Stand user interface	C-arm Stand user interface based on hard keys and a small monochrome display	C-arm Stand touch screen user interface	The hard-key based interface on the predicate device has been replaced with a touch-screen based stand user interface This feature is reused from the reference device *Veradius Unity* (K142708). This change 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, IEC60601-1-2 for Electromagnetic compatibility, IEC62366 for application of usability engineering. This change does not affect safety or effectiveness of the device. Thus, demonstrating substantial equivalence
Manual Outline	Not Present	Manual outlining	With this so-called Manual Outline function, it is possible to draw lines and dots on an overlay of the clinical image with help of the finger, stylus pen or mouse. It is not related to diagnostics. This feature is reused from the reference device Veradius *Unity* (K142708). The changes do not introduce new risks or change any of the existing risks compared to the predicate device. This change does not affect safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Wireless footswitch	Not Present	Wireless footswitch	Next to the wired footswitch and optional wireless footswitch can be used with the system. This wireless footswitch is reused from reference device *Veradius Unity* (K142708). The change does not introduce new risks, but only minor update to existing risks compared to the predicate device. This change does not affect safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
DICOM connectivity	Current DICOM connectivity	Improved DICOM connectivity workflow • Easier selection of patient data for export • Introduced unattended network transfer of export jobs • Integrated workflow for export to local	The improvements are ease-of-use improvements, fully compliant with the DICOM standard and do not impact clinical functionality. The changes are shown to be compliant with the international and FDA recognized standard IEC62366 for application of usability engineering. Therefore, this change does not impact safety or effectiveness of the

		media (USB and DICOM DVD) • Improved workflow for multimodality viewer functionality • Improved DICOM transfer speed	device. Thus, demonstrating substantially equivalent
X-ray tube heat management	Current X-ray tube heat management	• Improved presentation to the user of tube and oil heating information • Reduced energy waste in non-x-ray (pump, stator)	These improvements allow minimizing non-x-ray wasted energy by updating the control functions for the oil pump and stator control and improve feedback to the user on tube and oil heat status. The changes have been evaluated in risk management, and they do not lead to new risks. The changes are shown to be compliant with the international and FDA recognized standard IEC62366 for application of usability engineering. This change does not impact clinical functionality. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
User Interface Mobile viewing station	Current User Interface Mobile viewing station	New identity look for MVS-UI. The Graphical User Interface look and feel of the mobile viewing station is changed to the Philips New Experience Identity look and feel.	These features are to improve the look and feel of the device and does not impact clinical functionality. The changes have been evaluated in risk management, and they do not lead to new risks. The changes are shown to be compliant with the international and FDA recognized standard IEC62366 for application of usability engineering. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantially equivalent.
Wired Footswitch and remote control unit	Current Wired Footswitch and remote control unit	The current wired footswitch, remote control unit are replaced with a new wired footswitch and new remote control	The current wired footswitch and remote control unit are replaced with a new wired footswitch and new remote control with identical functionality. This change does not impact clinical functionality. These features are to improve the look and

		with identical functionality	feel of the device and does not impact clinical functionality. The changes have been evaluated in risk management, and they do not lead to new risks. The changes are shown to be compliant with the international and FDA recognized standard IEC 62366 for application of usability engineering. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
RAD (radiography)	RAD support (Optional)	RAD not supported	The removal of RAD (radiography) is evaluated in risk management The change does not introduce new risks Therefore; this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Live DVD Recording	Live DVD recording support (Optional)	Live DVD recording option not supported	The removal of Live DVD recording is evaluated in risk management The change does not introduce new risks Therefore; this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Security features	Current Security features	Introduction of the security features • Local user account management o Function improved to enable a username/password combination. • Network time synchronization o Different implementation only • Audit trail • White listing • DIACAP hardening • Disk encryption • FIPS 140-2	These features are to improve security of the device and do not impact clinical functionality. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Introduction of metal exclusion	Not present	Metal exclusion added	The feature is to minimize the impact of added metal in the X-ray image by excluding metal (black

			exclusion) from the automatic exposure control. It has the same design as the currently available BodySmart (white exclusion) function of the predicate device. This change was shown to be compliant with the international and FDA recognized standards IEC60601-2-43 and IEC60601-2-54 for basic safety and essential performance. Thus, demonstrating substantial equivalence
System service functions	Current System service functions	• BV-scope field service infrastructure is replaced by Philips Support Connect field service infrastructure. • Introduction of PSC implies also that the Service UI is located on the target machine itself, and thus enabling access to field service functionality via the MVS-UI. • Using CAT tool to view logging. • All field service procedures are migrated to the PSC based field service infrastructure	The change is only impacting the service interface and has no clinical impact. Therefore this change does not impact safety or effectiveness of the device Thus, demonstrating substantial equivalence
Room Interface	Not Present	External x-ray and power indication interface	This feature is to optionally allow connecting an external x-ray and power lamp to the system and does not impact clinical functionality. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Audible signals	Audible signals with fixed volume	Speaker with volume control added in the Stand	This feature is to allow control of the volume produced by the system for audible signals. This change does not impact clinical functionality. Therefore, this change does not

			impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.
Analogue video out	original	Analogue video out no longer supported	The analog video-out was used to connect external monitors. This is an outdated video interface and has been removed. This change does not impact clinical functionality. Therefore, this change does not impact safety or effectiveness of the device. Thus, demonstrating substantial equivalence.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed **Zenition 50** and 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
- Guidance for Industry and FDA Staff -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, 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 50** :

- 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 50** did not require clinical study since substantial equivalence to the primary currently marketed and predicate device BV Pulsera was demonstrated with the following attributes:

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

Substantial Equivalence Conclusion:

The **Zenition 50** is substantial equivalent to the currently marketed predicate device *BV Pulsera* K010435 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 50** 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.