



May 22, 2024

Philips Medical Systems Nederlands B.V.  
% Rahul Kumar Sinha  
Regulatory Approbation Officer  
Veenpluis 6  
Best, NB 5684 PC  
NETHERLANDS

Re: K240224

Trade/Device Name: Zenition 90  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-Intensified Fluoroscopic X-Ray System  
Regulatory Class: Class II  
Product Code: OWB, JAA, OXO  
Dated: January 25, 2024  
Received: April 22, 2024

Dear Rahul Kumar Sinha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A stylized signature of "Lu Jiang" in black cursive script, overlaid on a large, light blue, semi-transparent "FDA" logo.

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiologic Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K240224

Device Name

Zenition 90

Indications for Use (Describe)

The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. 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) Number: K240224

## **510 (k) Summary**

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The 510(k) Summary is given in the below pages.

**510(k) Summary****K240224**

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

**Date Prepared** January 25, 2024

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

**Primary Contact Person:** Rahul Kumar Sinha  
Regulatory Approbation Officer  
Phone: +91 9940259360  
E-mail: [rahulkumar.sinha@philips.com](mailto:rahulkumar.sinha@philips.com)

**Secondary Contact Person:** Neena Sonavane  
Regulatory Affairs Leader  
Phone: +91-8446020023  
E-mail: [neena.sonavane@philips.com](mailto:neena.sonavane@philips.com)

|                |                            |                                             |
|----------------|----------------------------|---------------------------------------------|
| <b>Device:</b> | Trade Name:                | <b>Zenition 90</b>                          |
|                | 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                                    |

|                                  |                            |                                             |
|----------------------------------|----------------------------|---------------------------------------------|
| <b>Primary Predicate Device:</b> | Trade Name:                | Zenition 70                                 |
|                                  | Manufacturer:              | Philips Medical Systems Nederland B.V.      |
|                                  | 510(k) Clearance:          | K212813                                     |
|                                  | 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 90** 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 90** is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. 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 90** demonstrates substantial equivalence with predicate Zenition 70 in terms of intended use, and do not raise questions of safety and effectiveness.

| Table 1. Indications for use comparison of the proposed Zenition 90 versus the currently marketed and predicate device, Zenition 70                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Predicate Device Zenition 70                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Proposed Zenition 90                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Conclusion                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Indications for Use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>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.</p> <p>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.</p> <p>Applications:</p> <ul style="list-style-type: none"> <li>• Orthopedic</li> <li>• Neuro</li> <li>• Abdominal</li> </ul> | <p>The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. 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.</p> <p>Applications:</p> <ul style="list-style-type: none"> <li>• Orthopedic</li> <li>• Neuro</li> <li>• Abdominal</li> <li>• Vascular</li> <li>• Thoracic</li> <li>• Cardiac</li> </ul> | <p><b><i>Substantially Equivalent SE analysis:</i></b><br/>Same</p> <p>The proposed <b>Zenition 90</b> is used for all patients including neonates (birth to one month). The safety and effectiveness is in line with FDA guidance “<i>Pediatric information for x-ray imaging device premarket notifications</i>”</p> <p>Therefore, proposed <b>Zenition 90</b> demonstrates substantial equivalence with predicate Zenition 70 in terms of intended use and is safe and effective.</p> |

|                                                                                                 |  |  |
|-------------------------------------------------------------------------------------------------|--|--|
| <ul style="list-style-type: none"><li>• Vascular</li><li>• Thoracic</li><li>• Cardiac</li></ul> |  |  |
|-------------------------------------------------------------------------------------------------|--|--|

**Fundamental  
Scientific  
Technology:**

The proposed **Zenition 90** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate Zenition 70. The technology used in the development of the major components of the proposed **Zenition 90**, which includes X-ray generator, X-ray tube housing assembly, and Image detection system is similar to the currently marketed and predicate Zenition 70.

**Table 2** shows that the proposed **Zenition 90** is considered substantially equivalent to the currently marketed predicate, *Zenition 70* in terms of major components and technological characteristics.

| <b>Table 2 Technological characteristics comparison of the currently marketed predicate device, Zenition 70 versus the proposed Zenition 90</b> |                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Component /feature</b>                                                                                                                       | <b>Currently market Zenition 70</b>                                                                                                                                                                                                           | <b>Proposed Zenition 90</b>                                                                                                                                                                                                                           | <b>Conclusion</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| C-arm motions and brakes                                                                                                                        | Manual                                                                                                                                                                                                                                        | Motorized                                                                                                                                                                                                                                             | <p>The c-arm movements are motorized in <b>Zenition 90</b> as against manual in Zenition 70. The Zenition 70 system provide manual brake levers to release and lock the brakes while <b>Zenition 90</b> system uses electromagnetic brakes to release or lock the c-arm axis to simplify the workflow.</p> <p>Motorized movement and the electromagnetic brakes are an added advantage in <b>Zenition 90</b> compared to the equivalent devices Zenition 70.</p> <p>Zenition 90 introduces motorized movement in 3 axis (angulation, rotation, and longitudinal) that are manual in Zenition 70.</p> <p><b>Conclusion:</b><br/>Similar and substantially equivalent</p> |
| X-ray Generator                                                                                                                                 | <p>-Peak output power: 15 kW</p> <p>-kV range: 40-120 kV</p> <p>-Maximum mA: 125 mA (at 15kW power)</p>                                                                                                                                       | <p>-Peak output power: 15kW/25kW</p> <p>- kV Range: 40 to 120kV</p> <p>-Maximum mA: 125 mA (at 15kW power)</p> <p>-Maximum mA: 208mA (at 25kW power)</p>                                                                                              | <p>The kV range of proposed <b>Zenition 90</b> is the same as compared to the predicate Zenition 70.</p> <p>The maximum mA of the <b>Zenition 90</b> (15kW) is the same compared to the Zenition 70.</p> <p>While in <b>Zenition 90</b> we also have a 25kW version, where higher mA is possible.</p> <p>Make of Generators are different in both the devices however, the technology, energy source and output are similar.</p> <p>This change does not impact the safety and effectiveness of the device. Thus, demonstrating substantial equivalence.</p> <p><b>Conclusion:</b><br/>Similar and substantially equivalent</p>                                         |
| <b>X-ray tube</b>                                                                                                                               | <p>-Rotating Anode (Model: RTM 780 H (Type RO-0306)</p> <p>-Focal spot: dual (0.3 &amp; 0.6)</p> <p>-Target angle: 10°</p> <p>-Anode heat content: 225kJ</p> <p>-Maximum anode cooling rate: 550W</p> <p>-Nominal anode input power: 15kW</p> | <p>- Rotating Anode (Model: RTM 780 H (Type RO-0306)</p> <p>Focal spot: dual (0.3 &amp; 0.6)</p> <p>Target angle: 10°</p> <p>Anode heat content: 225kJ</p> <p>Maximum anode cooling rate: 550W</p> <p>-Nominal anode input power: 15kW</p> <p>and</p> | <p>The design and characteristics of X-ray tube of subject device <b>Zenition 90</b> and the predicate device Zenition 70 are the same and from same supplier.</p> <p><b>Conclusion:</b><br/>Same and substantially equivalent</p>                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                                |                                               |                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------|-----------------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                |                                               | -Nominal anode input power: 25kW            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Monoblock</b>                               |                                               |                                             | The Monoblock is the combination of x-ray tube, transformer, cooling oil and oil pump.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Oil circulation                                | Active oil circulation with AC Pump           | Active oil circulation with DC Pump         | <p>The proposed device <b>Zenition 90</b> has similar heat performance compared to the predicate device Zenition 70. There are no technological significant difference in the safety and clinical performance of the devices.</p> <p>Proposed device <b>Zenition 90</b> uses DC oil pump while the predicate Zenition 70 uses AC oil pump. DC Pump in Zenition 90 helps for better Oil circulation with lower power consumption which results in lower energy losses.</p> <p>Both the devices Zenition 70 and <b>Zenition 90</b> use the same safety mechanism of thermal switch to address undesirable overheating scenarios.</p> <p><b>Conclusion:</b><br/>Same and substantially equivalent</p> |
| Monoblock heat content                         | Monoblock heat content: 1350kJ                | Monoblock heat content: 1350kJ              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Safety mechanisms                              | Safety mechanisms: Thermal Switch             | Safety mechanisms: Thermal Switch           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Inherent filtration                            | filtration                                    | filtration                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Fluoro time                                    | fluoro time: 296W for 60mins                  | fluoro time: 296W for 60mins                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Flat Panel Detector / Image Intensifier</b> |                                               |                                             | The subject device <b>Zenition 90</b> uses the same flat panel detector which has been previously cleared in predicate device Zenition 70 (K212813) and sourced from the same supplier.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| - Frame rate                                   | Frame rate: 30fps                             | Frame rate: 30fps                           | <p><b>Conclusion:</b><br/>Same and substantially equivalent</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| - Zoom modes                                   | Zoom modes: Overview mode + 2 zoom modes      | Zoom modes: Overview mode + 2 zoom modes    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| - Detector size ( x/y)                         | -Detector size (x/y): 207mm x 207mm (square)  | Detector size (x/y): 207mm x 207mm (square) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                                | - Detector size (x/y): 301mm x 301mm (square) | Detector size (x/y): 301mm x 301mm (square) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| - Pixel pitch                                  | pixel pitch: 154 µm                           | pixel pitch: 154 µm                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| - Image matrix                                 | Image matrix: 1344x1344<br>DQE: 77%           | Image matrix: 1344x1344<br>DQE: 77%         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| - "Detector quantum efficiency (DQE)           | Pixel pitch: 154µm                            | Pixel pitch: 154µm                          | <p><b>Conclusion:</b><br/>Same and substantially equivalent</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                                | Image matrix: 1000x1000<br>DQE: 77%           | Image matrix: 1000x1000<br>DQE: 77%         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Imaging Processing technology</b>           | Xres-3                                        | Xres-3                                      | The predicate device Zenition 70 and the proposed device <b>Zenition 90</b> both use the same PC-based platform, and algorithm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|                                          |                                                                                                                                                                                                |                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                          |                                                                                                                                                                                                |                                                                                                                                                                                                | <b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Anti Scatter Grid</b>                 | Removable grid (square)<br><br>Transmission: 70%                                                                                                                                               | Removable grid (square)<br><br>Transmission: 70%                                                                                                                                               | The proposed <b>Zenition 90</b> has same as of predicate Zenition 70<br><br><b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Radiation safety features</b>         | Collimation<br><br>Anti-scatter grid<br><br>Fluoroscopy modes<br><br>Pulsed fluoroscopy<br><br>Recording and storing fluoroscopic runs<br><br>Last image hold<br><br>Real-time dose monitoring | Collimation<br><br>Anti-scatter grid<br><br>Fluoroscopy modes<br><br>Pulsed fluoroscopy<br><br>Recording and storing fluoroscopic runs<br><br>Last image hold<br><br>Real-time dose monitoring | Both the proposed device <b>Zenition 90</b> and the predicate device Zenition 70 share the same radiation safety features.<br><br><b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Beam Limiting Device (Collimator)</b> | Square (but round in zooming and rotation)                                                                                                                                                     | Square (but round in zooming and rotation)                                                                                                                                                     | The proposed <b>Zenition 90</b> system uses the same collimator as is in predicate device Zenition 70.<br><br><b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Geometry</b>                          | Hammerhead design<br>Length : 206 x 82 x 162 cm<br><br>Weight: 332 Kg<br><br>Stand-U/I: 15.3" touch screen display                                                                             | New design stand<br>Size: 206 x 82 x 162 cm<br><br>Weight:<br>400 kg (Motorized)<br>375 Kg (Non-motorized)<br><br>Stand-U/I: 15.3" touch screen display                                        | The proposed <b>Zenition 90</b> new stand design comes with lower C-arm operating forces, provision to mount additional User Interface monitor. This helps in maneuverability and ease of use.<br><br>The Proposed <b>Zenition 90</b> stand brings higher weight (400 kg) due to motorization in comparison with Zenition 70 (<350), even though c-arm axis movements by Motorization simplify the workflow and improves user experience, no impact on Clinical workflow.<br><br>The stand UI display (15.3") is same in the proposed Zenition 90 and the predicate Zenition 70.<br><br><b>Conclusion:</b><br>Similar and substantially equivalent |
| <b>System architecture</b>               | PC Based Win 10                                                                                                                                                                                | PC Based Win 10                                                                                                                                                                                | <b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Ionizing radiation</b>                | System uses X-ray for imaging                                                                                                                                                                  | System uses X-ray for imaging                                                                                                                                                                  | Same X-ray technology usage<br><b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Laser Alignment tool</b>              | Tube Laser Aiming Device (Model: 4598 008 4322x)                                                                                                                                               | Tube Laser Aiming Device (Model: 4598 008 4322x)                                                                                                                                               | <b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>DICOM connectivity</b>                | DICOM connectivity workflow                                                                                                                                                                    | DICOM connectivity workflow                                                                                                                                                                    | <b>Conclusion:</b><br>Same and substantially equivalent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

|                                                       |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                       | <ul style="list-style-type: none"> <li>-Easier selection of patient data for export</li> <li>-Introduced unattended network transfer of export jobs</li> <li>-Integrated workflow for export to local media (USB and DICOM DVD)</li> <li>-Improved workflow for multimodality viewer functionality</li> <li>- DICOM transfer speed</li> </ul>                  | <ul style="list-style-type: none"> <li>-Easier selection of patient data for export</li> <li>-Introduced unattended network transfer of export jobs</li> <li>-Integrated workflow for export to local media (USB and DICOM DVD)</li> <li>-Improved workflow for multimodality viewer functionality</li> <li>- Same DICOM transfer speed</li> </ul>             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Security features</b>                              | <ul style="list-style-type: none"> <li>-Local user account management</li> <li>-Function improved to enable a username/password combination.</li> <li>-Network time synchronization</li> <li>-Different implementation only</li> <li>-Audit trail</li> <li>-White listing</li> <li>-DIACAP hardening</li> <li>-Disk encryption</li> <li>-FIPS 140-2</li> </ul> | <ul style="list-style-type: none"> <li>-Local user account management</li> <li>-Function improved to enable a username/password combination.</li> <li>-Network time synchronization</li> <li>-Different implementation only</li> <li>-Audit trail</li> <li>-White listing</li> <li>-DIACAP hardening</li> <li>-Disk encryption</li> <li>-FIPS 140-2</li> </ul> | <b>Conclusion:</b><br>Same and substantially equivalent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Room Interface (Xray Indication + Input Power)</b> | External x-ray Lamp and power indication interface                                                                                                                                                                                                                                                                                                             | External x-ray Lamp and power indication interface                                                                                                                                                                                                                                                                                                             | <b>Conclusion:</b><br>Same and substantially equivalent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Audible signals</b>                                | Speaker with volume control added in the Stand                                                                                                                                                                                                                                                                                                                 | Speaker with volume control added in the Stand                                                                                                                                                                                                                                                                                                                 | <b>Conclusion:</b><br>Same and substantially equivalent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Wired Footswitch and remote control unit</b>       | Same                                                                                                                                                                                                                                                                                                                                                           | Same                                                                                                                                                                                                                                                                                                                                                           | <b>Conclusion:</b><br>Same and substantially equivalent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Automatic Vascular outlining (AVO)</b>             | Manual Outlining - User can manually get the vascular outline for region of interest                                                                                                                                                                                                                                                                           | Manual and automatic                                                                                                                                                                                                                                                                                                                                           | <p>Both <b>Zenition 90</b> and Zenition 70 provide manual vascular outlining. In addition, <b>Zenition 90</b> introduces automatic vascular outlining, where the user can get a vascular outline by a single click on UI. The operator is able to manually adjust the outline, re-draw it, or hide it at any time. Additionally, manual vascular outlining is always available to the user. Therefore, the change introduced in <b>Zenition 90</b> is aimed to improve ease of use. Clinical workflow is the same in both manual or automatic vascular outlining.</p> <p>The Manual outlining in <b>Zenition 90</b> is similar with the predicate Zenition 70.</p> |

|                           |                                                                                      |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                           |                                                                                      |                                                                                                                                   | <p>The automatic vascular outlining is an added advantage for ease of use in <b>Zenition 90</b>.</p> <p>Thus, there is no significant difference in the safety and effectiveness of the devices.</p> <p><b>Conclusion:</b><br/>Similar and substantially equivalent.</p>                                                                                                                                                                                                                                                                                                                  |
| <b>Injector interface</b> | Manual Injection possible. User can manually add X-ray delay from an injector device | Integrated injector interface where user can add needed X-ray delay based on Injection volume. Manual Injection is also possible. | <p>Manual Injector is always possible in both the systems the proposed <b>Zenition 90</b> as well as the equivalent device Zenition 70. In addition to manual injector, <b>Zenition 90</b> has provision to connect an external injector, so the user can add X-ray start delay time based on injection volume. Hence, clinically, no change is introduced in the workflow by using integrated Injector interface.</p> <p>Thus, there is no significant difference in the safety and effectiveness of the devices</p> <p><b>Conclusion:</b><br/>Similar and substantially equivalent.</p> |

Based on the information provided above, the **Zenition 90** is considered substantially equivalent to the currently marketed predicate Zenition 70 in terms of fundamental scientific technology.

**Summary of  
Non-Clinical  
Performance  
Data:**

Non-clinical performance testing has been performed on the proposed **Zenition 90** and it demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.2 2020-08). FDA/CDRH recognition number 19-49.
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) FDA/CDRH recognition number 19-4
- IEC 60601-2-43 - Particular requirements for the safety of X-Ray equipment for interventional procedures (Edition 2.2, 2019). FDA/CDRH recognition number 12-329.
- 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 1.2 2018). FDA/CDRH recognition number 12-317.
- 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 4.1 2020). FDA/CDRH recognition number 19-36.
- 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 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 3.0, corrected version, 2019). FDA/CDRH recognition number 5-125.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.1 2020-06 CONSOLIDATED VERSION). FDA/CDRH recognition number 5-129
- Pediatric information for x-ray imaging device premarket notifications, Nov 28, 2017 (document number 1771)
- Content of Premarket Submissions for Device Software Functions, June 14, 2023 (document number GUI00000337)
- Applying Human Factors and Usability Engineering to Medical Devices, Feb 03, 2016 (document number 1757)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 27, 2023 (document number GUI00001825)
- Radio frequency wireless technology in medical devices- Guidance for Industry and Food and Drug Administration Staff, Aug 14, 2013 (document number 1618).
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff, Sep 01, 2016 (document number 644)

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. The Subject device **Zenition 90** meets the acceptance criteria and is adequate for its intended use.

**Substantial  
Equivalence  
Conclusion:**

The **Zenition 90** is substantial equivalent to the currently marketed predicate device *Zenition 70* (K212813), in terms of indications for use, fundamental scientific technology, safety and effectiveness.