



December 15, 2023

Ziehm Imaging GmbH  
c/o Tsvetelina Milanova  
Specialist Regulatory Affairs  
Lina-Ammon-Strasse 10  
Nuremberg, Bavaria 90471  
GERMANY

Re: K231700

Trade/Device Name: Ziehm Vision FD  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: Class II  
Product Code: OWB, JAA  
Dated: November 23, 2023  
Received: November 24, 2023

Dear Ms. Milanova:

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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A stylized signature of "Lu Jiang" in blue ink, with a large, light blue "FDA" watermark in the background.

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiological 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

510(k) Number (if known)

K231700

Device Name

Ziehm Vision FD

### Indications for Use (Describe)

The Ziehm Vision FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy procedures.

The visualization of such anatomical structures assists the clinician in the clinical outcome. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

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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# 510k Summary - K231700

November, 23 2023

In accordance with 21 CFR §807.92 the following 510(k) summary information is provided:

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US Agent Kevin Bridgman  
VP Quality Assurance & Regulatory Affairs  
Ziehm-Orthoscan, Inc.  
14555 N 82nd St  
Scottsdale AZ, 85260

Device (Trade Name): Ziehm Vision FD

Common /Usual Names: Mobile Fluoroscopic C-Arm

Regulation: 21CFR 892.1650

Regulation Description: Image-intensified fluoroscopic x-ray system

Product Code: OWB , JAA

Product Class: II

Predicate Device: K193230 Ziehm Vision FD

Decision Date: 20/12/2019

Regulation: 21CFR 892.1650

Regulation Description Name: Image-intensified fluoroscopic x-ray system

Product Code: JAA; OWB

Device Class: II

Summary of  
Technological  
Characteristics

The Ziehm Vision FD mobile fluoroscopy system is comprised of a mobile stand with a C-Profile shaped support with both a mono-block high voltage generator assembly and Flat Panel image receptor. These attach to either end of a C-Profile providing a fixed SID. The device performs 2D medical imaging using 4 axes of manual movement and one vertical axes of motorized movement. A user touch screen provides for concise user selectable anatomical programs and X-ray technique control. Integrated high-resolution flat panel display monitors directly mounted on the monitor cart providing the clinician with a precise angle for visualization of live fluoroscopic images of the patient's anatomy. This visualization helps to localize regions of pathology for surgical procedures. The mobile stand supports both a cable bound and optional wireless fluoroscopic footswitch. The Wireless footswitch operation allows for optimum positioning for the surgeon by removing the cable on the floor. The optional interface panel of the Ziehm Vision FD provides connection of peripheral devices such as external monitors, thermal video printers, and image storage devices (USB, DVD) and DICOM fixed wire and wireless network interfaces.

The proposed modified device Ziehm Vision FD employs the same fundamental control, and substantially equivalent scientific technology as that of our predicate device Ziehm Vision FD (K193230). Software architecture design is substantially equivalent to that of the predicate Ziehm Vision FD.

The primary modification of the C-Arm includes an 8 inch IGZO (Indium gallium zinc oxide) flat panel detector (FPD). The new 8 inch IGZO FPD is an addition to already introduced CMOS and a-Si FPD. The flat panel detectors have the same outer product design of the housing, both devices use safety shielding for radiation suppression and use solid state x-ray image receptors (SSXI / FPD) 8 inch CMOS, 12 inch a-Si and the only difference to the predicate Ziehm Vision FD is the additional 8 inch IGZO panel.

The comparison of the predicate device and the modified devices shows that the scientific and technical characteristics of the Ziehm Vision FD are

substantially equivalent as those of the Ziehm Vision FD predicate device (K193230).

**Intended Use** The Ziehm Vision FD is a mobile C-arm providing image data by means of a non-contact noninvasive x-ray technique during medical procedures and stores them temporarily. The Ziehm Vision FD is intended for use in all medical indications requiring fluoroscopy.

The system is intended for use with human beings of any age. It is the physician's responsibility to decide whether to use the system with infants, children and adipose patients.

The system is intended for use with human bodies covering such structures but not limited to the following, e.g. organs, tissue, bones, implants depending on the medical indication.

**Indications for Use:** The Ziehm Vision FD is intended for use in providing medical imaging for adults and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides contactless fluoroscopic image capture, temporarily storing, and display of digital subtraction, and acquisition of cine loops during diagnostic, interventional and surgical procedures. Examples of clinical application may include pediatric, cholangiography, endoscopic, urologic, lithotripsy, orthopedic, neurologic, vascular, cardiac, angiographic, critical care, and emergency room fluoroscopy procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

### **Device Comparison Table**

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

| <b>Model</b>  | <b>Modified Ziehm Vision FD</b>                                                                                       | <b>Predicate Ziehm Vision FD (K193230)</b>                                                                            | <b>Comparable Properties Substantial Equivalence Discussion</b> |
|---------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| 510(k) Number | K231700                                                                                                               | K193230                                                                                                               | -                                                               |
| Product Codes | OWB (interventional fluoroscopic x-ray system)<br>Subsequent:<br>JAA (system, x-ray, fluoroscopic, image-intensified) | OWB (interventional fluoroscopic x-ray system)<br>Subsequent:<br>JAA (system, x-ray, fluoroscopic, image-intensified) | Identical                                                       |

| Model                                           | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                      | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device<br>Image/<br>General<br>Overview         | <br>Ziehm Vision FD 8"x 8"<br><br>Ziehm Vision FD 12"x 12"               | <br>Ziehm Vision FD 8"x 8"<br><br>Ziehm Vision FD 12"x 12"                              | <p>The modified Ziehm Vision FD and the predicate Ziehm Vision FD (K193230) share the same outer design.</p> <p>The flat panel detectors are identical in the design of the housing, both devices use safety shielding for radiation suppression and use solid state x-ray image receptors (SSXI / FPD) 12 inch aSi, 8 inch CMOS and the difference to the predicate Ziehm Vision FD is the new 8 inch IGZO FPD.</p> <p>The 8 inch and 12 inch a-Si Varex FPD's have been discontinued.</p> |
| <b>X-ray Generator</b>                          |                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Maximum<br>Output                               | Variant A0: 2.0 kW<br>Variant A1: 2.4 kW                                                                                                                                                                                                   | Variant A0: 2.0 kW<br>Variant A1: 2.4 kW                                                                                                                                                                                                                    | Identical.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Pulsed<br>Fluoroscopy:<br>Pulse and<br>Duration | <ul style="list-style-type: none"> <li>pulse width:<br/>7 - 23 ms (12" FPD)<br/>10 - 40 ms (8" FPD)</li> <li>pulse rate:<br/>1, 2, 4, 8, 12.5, 25<br/>pulse/s (8" and 12"<br/>FPD)<br/>1, 2, 5, 10, 15, 30<br/>pulse/s (8" FPD)</li> </ul> | <ul style="list-style-type: none"> <li>pulse width:<br/>7 - 23 ms (12" FPD<br/>Fujifilm aSi)<br/>10 - 40 ms (12" FPD<br/>Varex, 8" FPD Varex<br/>aSi/CMOS)</li> <li>pulse rate:<br/>1, 2, 4, 8, 12.5, 25 pulse/s<br/>1, 2, 5, 10, 15, 30 pulse/s</li> </ul> | <p>Substantial equivalence.</p> <p>The 8 inch and 12 inch a-Si Varex FPD's have been discontinued..</p>                                                                                                                                                                                                                                                                                                                                                                                     |

| Model                                                         | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                        | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Digital<br>Radiography<br>(Snapshot) /<br>Operating<br>Values | <ul style="list-style-type: none"> <li><u>Variant A0:</u><br/>kV range: 40 - 110 kV<br/>mA range: up to 20 mA</li> <li><u>Variant A1:</u><br/>kV range: 40 - 120 kV<br/>mA range: up to 24 mA<br/>(8" and 12" FPD)</li> </ul>                                                                                                                                                                                                                                                                                                         | <ul style="list-style-type: none"> <li><u>Variant A0:</u><br/>kV range: 40 -110 kV<br/>mA range: up to 20 mA</li> <li><u>Variant A1:</u><br/>kV range: 40 - 120 kV<br/>mA range: up to 20 mA (8"<br/>FPD Varex aSi)<br/>mA range: up to 24 mA (8"<br/>FPD Varex<br/>CMOS, 12" FPD Varex aSi,<br/>12" FPD Fujifilm aSi)</li> </ul>                                             | Substantial equivalence.<br>The 8 inch and 12 inch a-Si<br>Varex FPD's have been<br>discontinued.                                                                                                                                                                                                                                                                                                                               |
| <b>Image Detector</b>                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Image<br>Detector                                             | <b>Flat Panel Detector</b><br>                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Flat Panel Detector</b><br>                                                                                                                                                                                                                                                            | Substantial equivalence.<br>They are identical in the outer<br>product design of the housing,<br>both devices use safety<br>shielding for radiation<br>suppression and use solid state<br>x-ray image receptor (SSXI /<br>FPD) The modified Ziehm Vision<br>FD has additionally new 8 inch<br>IGZO (Indium gallium zinc<br>oxide) flat panel detector.<br>The 8 inch and 12 inch a-Si<br>Varex FPD's have been<br>discontinued. |
| Detector<br>Technology                                        | <u>Variant aSi FPD:</u> <ul style="list-style-type: none"> <li>Type: Amorphous Silicon<br/>Flat Panel Detector (aSi)</li> <li>Scintillator: Cesium-<br/>Iodide (CsI)</li> </ul> <u>Variant CMOS FPD:</u> <ul style="list-style-type: none"> <li>Type: Complementary<br/>Metal Semi-conductor)</li> <li>Scintillator: Cesium-<br/>Iodide (CsI)</li> </ul> <u>Variant IGZO FDP:</u> <ul style="list-style-type: none"> <li><b>Type: Indium gallium<br/>zinc oxide</b></li> <li><b>Scintillator: Cesium-<br/>Iodide (CsI)</b></li> </ul> | <u>Variant aSi FPD:</u> <ul style="list-style-type: none"> <li><u>Type: Amorphous Silicon<br/>Flat Panel Detector (aSi)</u></li> <li><u>Scintillator: Cesium-Iodide<br/>(CsI)</u></li> </ul> <u>Variant CMOS FPD:</u> <ul style="list-style-type: none"> <li><u>Type: Complementary Metal<br/>Semi-conductor)</u><br/><u>Scintillator: Cesium-Iodide<br/>(CsI)</u></li> </ul> | Substantial equivalence.<br>IGZO based detectors are<br>manufactured using processes<br>that are similar to aSi<br>detectors. The slight differences<br>in used sensor glass technology<br>does not have influence on<br>safety and effectiveness of the<br>C-arm product.                                                                                                                                                      |

| Model             | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Detector<br>Sizes | <p><u>Variant 21cm x 21cm (8"x8") CMOS:</u></p> <ul style="list-style-type: none"> <li>Size: 21 cm x 21 cm</li> <li>Detector matrix: 2,053 x 2,051 pixels</li> <li>Magnifier 1: 1,536 x 1,536 pixels</li> <li>Magnifier 2: 1,024 x 1,024 pixels</li> <li>Dynamic Range: <ul style="list-style-type: none"> <li>1 x 1 binning: 84 dB</li> <li>1 x 2 binning: 95 dB</li> </ul> </li> <li>System resolution (Nyquist): 5 lp/mm</li> </ul> <p><u>Variant 31cm x 31cm (12"x12") aSi:</u></p> <ul style="list-style-type: none"> <li>Size: 31 cm x 31 cm</li> <li>Detector matrix: 2,048 x 2,048 pixels</li> <li>Magnifier 1: 1,536 x 1,536 pixels</li> <li>Magnifier 2: 1,024 x 1,024 pixels</li> <li>Dynamic Range: ≥86 dB</li> <li>System resolution (Nyquist): 3.3 lp/mm</li> </ul> <p><b><u>Variant 21cm x 21cm (8"x8") IGZO:</u></b></p> <ul style="list-style-type: none"> <li><b>Size: 21 cm x 21 cm</b></li> <li><b>Detector matrix: 1,536 x 1,536 pixels</b></li> <li><b>Magnifier 1: 1,024 x 1,024 pixels</b></li> <li><b>Magnifier 2: 768 x 768 pixels</b></li> <li><b>System resolution (Nyquist): 3.7 lp/mm</b></li> </ul> | <p><u>Variant 20.5cm x 20.5cm (8"x8") CMOS:</u></p> <ul style="list-style-type: none"> <li>Size: 20.5 cm x 20.5 cm</li> <li>Detector matrix: 2,048 x 2,048 pixels</li> <li>Magnifier 1: 1,536 x 1,536 pixels</li> <li>Magnifier 2: 1,024 x 1,024 pixels</li> <li>Dynamic Range: <ul style="list-style-type: none"> <li>1 x 1 binning: 84 dB</li> <li>1 x 2 binning: 95 dB</li> </ul> </li> <li>System resolution (Nyquist): 5 lp/mm</li> </ul> <p><u>Variant 20cm x 20cm (8"x8") aSi:</u></p> <ul style="list-style-type: none"> <li>Size: 19.9 cm x 19.9 cm</li> <li>Detector matrix: 1,024 x 1,024 pixels</li> <li>Magnifier 1: 768 x 768 pixels</li> <li>Magnifier 2: 512 x 512 pixels</li> <li>Dynamic Range: 94 dB</li> <li>System resolution: 2.6 lp/mm</li> </ul> <p><u>Variant 30cm x 30cm (12"x12") aSi:</u></p> <ul style="list-style-type: none"> <li>Size: 29.8 cm x 29.8 cm</li> <li>Detector matrix: 1,536 x 1,536 pixels</li> <li>Magnifier 1: 1,024 x 1,024 pixels</li> <li>Magnifier 2: 768 x 768 pixels</li> <li>Dynamic Range: 94 dB</li> <li>System resolution (Nyquist): 2.6 lp/mm</li> </ul> <p><u>Variant 30.7 cm x 30.7 cm (12"x12") aSi:</u></p> <ul style="list-style-type: none"> <li>Size: 31 cm x 31 cm</li> <li>Detector matrix: 2,048 x 2,048 pixels</li> <li>Magnifier 1: 1,536 x 1,536 pixels</li> </ul> | <p>Substantial equivalence.</p> <p>The active pixel area of the detector types are not identical but are very similar in image area of approx. 8 inch x 8 inch. The modified device Ziehm Vision FD with IGZO has a higher resolution size in comparison to predicate device with 8 inch a-Si FPD, which leads to better image quality. All other differences with regard to the used technology have no influence on safety and effectiveness of the C arm.</p> <p>Variant 20cm x 20cm (8"x8") aSi and Variant 30cm x 30cm (12"x12") aSi were discontinued.</p> |

| Model                                | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                  | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                          | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                      |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                      |                                                                                                                                                                                                                                                                                                                                                                              | <ul style="list-style-type: none"> <li>Magnifier 2:<br/>1,024 x 1,024 pixels</li> <li>System resolution<br/>(Nyquist):<br/>3.3 lp/mm</li> </ul>                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                     |
| <b>Anti-Scatter Grids</b>            |                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                     |
| Fixed anti-scatter grid              | fixed anti-scatter grid:<br><br>CMOS (8inch) <ul style="list-style-type: none"> <li>Pb 8:1/70 lines/cm</li> </ul> <b>IGZO (8inch)</b> <ul style="list-style-type: none"> <li><b>Pb 8:1/70 lines/cm</b></li> </ul>                                                                                                                                                            | fixed anti-scatter grid:<br><br>CMOS (8inch) <ul style="list-style-type: none"> <li>Pb 8/70</li> </ul>                                                                                                                                                                                                                                                          | Substantial equivalence.<br>The grids for the CMOS and the IGZO FPD are identical for the predicate and the modified Ziehm Vision FD.                                                                                                                                                                                               |
| optional removable anti-scatter grid | Removable Grid:<br>CMOS (8inch) <ul style="list-style-type: none"> <li>Pb 8:1/70 lines/cm</li> </ul> a-Si (12inch) <ul style="list-style-type: none"> <li>Pb 6:1 /80 lines/cm</li> </ul> <b>IGZO (8inch)</b> <ul style="list-style-type: none"> <li><b>Pb 8:1/70 lines/cm</b></li> </ul>  | Removable Grid:<br>CMOS (8inch) <ul style="list-style-type: none"> <li>Pb 8:1/70 lines/cm</li> </ul> a-Si (8inch) <ul style="list-style-type: none"> <li>Pb 8:1/70 lines/cm</li> </ul> a-Si (12inch) <ul style="list-style-type: none"> <li>Pb 6:1 /80 lines/cm</li> </ul>  | Substantial equivalence.<br>The grids for the CMOS and the IGZO FPD are identical for the predicate and the modified Ziehm Vision FD. The grid of the a-Si (12 inch) FPD has a slightly different value compared to the anti-scatter grids for the other two FPD's. The 8 inch and 12 inch a-Si Varex FPD's have been discontinued. |
| <b>Mechanics</b>                     |                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                     |

| Model                                | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                       | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Length of<br>Mobile Stand            | <ul style="list-style-type: none"> <li>IGZO &amp; CMOS (8''): 174 cm/196 cm</li> <li>aSi (12''): 176 cm / 198 cm</li> </ul>                                                                                                                                                                                                                                       | <ul style="list-style-type: none"> <li>160 / 182 cm (20/20 135° orbital)</li> <li>CMOS (8''): 180 / 202 cm (orbital with lifting column expansion)</li> <li>aSi (12''): 176 / 198 cm</li> </ul>                                                                                                                                                                                                                       | <p>Substantial equivalence.</p> <p>Ziehm Vision FD 8'' a-Si, the length of 160 / 182 cm (20/20 135° orbital) for Ziehm Vision FD a-Si 8'' and the optional orbital length with lifting column expansion were discontinued.</p> <p>The length of Mobile Stand for Ziehm Vision FD 8'' CMOS has been optimized and does not have influence on the safety and effectiveness of the C-arm.</p> |
| Height of<br>Mobile Stand            | <ul style="list-style-type: none"> <li>IGZO, CMOS and a-Si: 155 / 197 cm</li> </ul>                                                                                                                                                                                                                                                                               | <ul style="list-style-type: none"> <li>a-Si (8''): 155 / 200 cm</li> <li>CMOS (8'') and a-Si (12''): 155 / 197 cm</li> <li>CMOS (8'') (optional): 158 / 220 cm (20/20 165° orbital with lifting column expansion)</li> </ul>                                                                                                                                                                                          | <p>Substantial equivalence.</p> <p>a-Si (8''): 155 / 200 cm and the option for CMOS (8''): 158 / 220 cm (20/20 165° orbital with lifting column expansion) were discontinued.</p>                                                                                                                                                                                                          |
| Weight                               | <p>Mobile Stand:</p> <ul style="list-style-type: none"> <li>max. 321 ± 5% kg (FD 8'')</li> <li>max. 326 ± 3% kg (FD 12'')</li> </ul> <p>Monitor Cart:</p> <ul style="list-style-type: none"> <li>156 kg ± 10%</li> </ul>                                                                                                                                          | <p>Mobile Stand:</p> <ul style="list-style-type: none"> <li>max. 321 ± 5% kg (FD 8'')</li> <li>max. 326 ± 3% kg (FD 12'')</li> </ul> <p>Monitor Cart:</p> <ul style="list-style-type: none"> <li>max 233 kg</li> </ul>                                                                                                                                                                                                | <p>Identical.</p> <p>The weight of the monitor cart of the predicate and the modified Ziehm Vision FD is identical. The value given before was a typing error.</p>                                                                                                                                                                                                                         |
| <b>Digital Image Processing</b>      |                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                            |
| Real-Time<br>processing<br>functions | <ul style="list-style-type: none"> <li>Recursive filter: 4 levels</li> <li>'Last Image Hold'</li> <li>Edge enhancement filter: 5 levels</li> <li>Windowing and step windowing</li> <li>Digital image rotation and reversal without radiation</li> <li>Grayscale inversion</li> <li>Virtual collimators</li> <li>Ziehm Adaptive Image Processing (ZAIP)</li> </ul> | <ul style="list-style-type: none"> <li>Recursive filter: 4 levels</li> <li>Stack filter ('Last Image Hold'): 5 levels</li> <li>'Last Image Hold'</li> <li>Edge enhancement filter: 5 levels</li> <li>Windowing and step windowing</li> <li>Digital image rotation and reversal without radiation</li> <li>Grayscale inversion</li> <li>Virtual collimators</li> <li>Ziehm Adaptive Image Processing (ZAIP)</li> </ul> | <p>Substantial equivalence.</p> <p>Stack filter ('Last Image Hold'): 5 levels has been discontinued.</p>                                                                                                                                                                                                                                                                                   |

| Model                                           | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                                                                                          |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Anatomical<br>Marking Tool<br>- AMT<br>(Option) | <ul style="list-style-type: none"> <li>Mark anatomical structures</li> <li>Indicate side of body</li> <li><b>Line and connected line</b></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <ul style="list-style-type: none"> <li>Mark anatomical structures</li> <li>Indicate side of body</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>Substantial equivalence.</p> <p>An optimization of the tool has been made and has no influence on the safety and effectiveness of the device.</p>                                                                                                                                                                                    |
| Data<br>Organization                            | <ul style="list-style-type: none"> <li>Patient-based data management with 16-image mosaic display</li> <li>Pre-registration via DICOM Worklist</li> <li>Manual input or emergency registration</li> <li>Calculated Dose Area Product (DAP)</li> <li>Optional: measured Dose Area Product (DAP)</li> <li>DAP value tagged to stored image</li> <li>Air Kerma dose display</li> <li>Air Kerma value tagged to stored image</li> <li>HIPAA security package (option)</li> <li><b>Video output</b> <ul style="list-style-type: none"> <li><b>Full HD SDI (split display)</b></li> <li><b>1920 x 1080p</b></li> <li><b>60Hz</b></li> </ul> </li> <li>Radiation Dose Structured Report (RDSR)</li> </ul> | <ul style="list-style-type: none"> <li>Patient-based data management with 16-image mosaic display</li> <li>Pre-registration via DICOM Worklist</li> <li>Manual input or emergency registration</li> <li>Calculated Dose Area Product (DAP)</li> <li>Optional: measured Dose Area Product (DAP)</li> <li>DAP value tagged to stored image</li> <li>Air Kerma dose display</li> <li>Air Kerma value tagged to stored image</li> <li>HIPAA security package (option)</li> <li>Radiation Dose Structured Report (RDSR)</li> </ul> | <p>Substantial equivalent.</p> <p>As required by the IEC 60601-2-43 the modified device Ziehm Vision FD displays dose area product (DAP), air kerma rate and cumulative air kerma at the same time.</p> <p>An optimization have been made through the Video output, which have no influence on the device safety and effectiveness.</p> |
| <b>Device Options List</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                         |
| Summary of<br>Options                           | <ul style="list-style-type: none"> <li>Removable anti-scatter grid</li> <li>Footswitch with customer-specific switch assignment: cable bound or wireless, with or without protective bracket</li> <li>Laser positioning device on the generator and/or detector</li> <li>Different sizes of display monitor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>Removable anti-scatter grid</li> <li>Footswitch with customer-specific switch assignment: cable bound or wireless, with or without protective bracket</li> <li>Laser positioning device on the generator and/or detector</li> <li>Different sizes of display monitor</li> <li>Monitor Arm: articulating monitor arm</li> </ul>                                                                                                                                                         | <p>Substantial equivalence.</p> <p>The option Z-Conference for video streaming and film for printing was discontinued.</p> <p>The option No 3.5" floppy disk drive and vertical 63 cm has been discontinued.</p>                                                                                                                        |

| Model | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Comparable Properties<br>Substantial Equivalence<br>Discussion |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
|       | <ul style="list-style-type: none"> <li>• Monitor Arm: articulating monitor arm</li> <li>• Additional handrails on C for orbital rotation support</li> <li>• Vertical lift: 42 cm</li> <li>• Dose Area Product (DAP) and Air Kerma: measured or calculated</li> <li>• Key switch Power on/off or X-ray on/off</li> <li>• Emergency stop button on the Monitor Cart</li> <li>• Printer: paper</li> <li>• USB port</li> <li>• DVD drive</li> <li>• Ziehm NetPort (DICOM 3.0 interface for digital network integration)</li> <li>• Ziehm NaviPort 2D (Interface for transfer of 2D image information to a navigation system; only in combination with DICOM 3.0 interface)</li> <li>• WLAN (interface for wireless data transfer)</li> <li>• Wireless Video (transmission of wireless video signal from the device to local display monitors)</li> <li>• Video connector(s): analog or digital signal</li> <li>• Application-Oriented Anatomical Programs</li> <li>• Measurement functions</li> <li>• Anatomical Marking Tool (AMT)</li> <li>• Vascular package</li> <li>• Cine loop: up to 25 frames per second</li> <li>• CO2 package (provides the option to use CO2 as contrast media for displaying vessels)</li> <li>• Generic interface to power injector</li> </ul> | <ul style="list-style-type: none"> <li>• Additional handrails on C for orbital rotation support</li> <li>• Vertical lift: 42 cm or 63 cm</li> <li>• Dose Area Product (DAP) and Air Kerma: measured or calculated</li> <li>• Key switch Power on/off or X-ray on/off</li> <li>• Emergency stop button on the Monitor Cart</li> <li>• Printer: paper or paper/film</li> <li>• USB port</li> <li>• DVD drive</li> <li>• No 3.5" floppy disk drive</li> <li>• Ziehm NetPort (DICOM 3.0 interface for digital network integration)</li> <li>• Ziehm NaviPort 2D (Interface for transfer of 2D image information to a navigation system; only in combination with DICOM 3.0 interface)</li> <li>• WLAN (interface for wireless data transfer)</li> <li>• Wireless Video (transmission of wireless video signal from the device to local display monitors)</li> <li>• Z-Conference (Video-server for streaming the live image of the left monitor within the hospital network)</li> <li>• Video connector(s): analog or digital signal</li> <li>• Application-Oriented Anatomical Programs</li> <li>• Measurement functions</li> <li>• Anatomical Marking Tool (AMT)</li> <li>• Subtraction modes DSA, MSA, RSA</li> <li>• Pixel shift and landmarking</li> <li>• Cine loop: up to 25 frames per second</li> <li>• CO2 package (provides the option to use CO2 as contrast media for displaying vessels)</li> </ul> |                                                                |

| Model                                    | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                              | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                                | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                                                                                 |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                          | <ul style="list-style-type: none"> <li>User administration (HIPAA)</li> <li>Interface for external separate X-ray indication lamp</li> <li>DICOM viewer software</li> <li>External display monitor</li> <li>Interface for Remote Vision Center</li> <li>Remote Vision Center</li> <li>Mounting bracket for Remote Vision Center</li> <li>Mobile Cart for Remote Vision Center</li> </ul> | <ul style="list-style-type: none"> <li>Generic interface to power injector</li> <li>User administration (HIPAA)</li> <li>Interface for external separate X-ray indication lamp</li> <li>DICOM viewer software</li> <li>External display monitor</li> <li>Interface for Remote Vision Center</li> <li>Remote Vision Center</li> <li>Mounting bracket for Remote Vision Center</li> <li>Mobile Cart for Remote Vision Center</li> </ul> |                                                                                                                                                                                                                                                                |
| Optional Accessories                     | <ul style="list-style-type: none"> <li>Sterile disposable covers</li> <li>Skin protection</li> </ul>                                                                                                                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>Sterile disposable covers</li> <li>Hand surgery table</li> <li>Skin protection</li> </ul>                                                                                                                                                                                                                                                                                                      | <p>Substantial equivalent</p> <p>The optional Hand surgery table is no longer available.</p> <p>Note: Ziehm Imaging GmbH is not the manufacturer of the optional accessories</p>                                                                               |
| <b>Software</b>                          |                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                |
| Level of Concern                         | <b>Enhanced</b>                                                                                                                                                                                                                                                                                                                                                                          | Moderate                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>Identical</p> <p>The term of level of concern has changed according to the Guidance "Content of Premarket Submissions for Device Software Functions", but there have been no additional changes to the device that have increased the level of concern.</p> |
| Software                                 | <ul style="list-style-type: none"> <li><b>Version 7.06.11</b></li> <li>Linux based OS Ubuntu</li> </ul>                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"> <li><b>Version 7.06 SP2</b></li> <li>Linux based OS Ubuntu</li> </ul>                                                                                                                                                                                                                                                                                                                              | <p>Substantial equivalence.</p> <p>Updates and optimization of software features, which does not have influence on safety and effectiveness of the device.</p> <p>For details please refer to Device Description_Ziehm Vision FD_revised.</p>                  |
| <b>Application / Indications for Use</b> |                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                |

| Model                  | Modified<br>Ziehm Vision FD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Predicate<br>Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Comparable Properties<br>Substantial Equivalence<br>Discussion                                                                                                                                 |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications<br>for Use | <p>The Ziehm Vision FD is intended for use in providing medical imaging for general populations. The device provides pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in Image geometry is required. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. <b>The system is not intended for use near MRI systems.</b></p> | <p>The Ziehm Vision FD is intended for use in providing medical imaging for general populations. The device provides pulsed and continuous fluoroscopic imaging of patients during diagnostic, interventional and surgical procedures. It is intended for use in visualizing complex anatomical structures and procedures such as vascular, cardiac, angiographic, cholangiography, endoscopic, urologic, orthopedic, neurologic, critical care, emergency room procedures, and where higher accuracy in Image geometry is required. This device does not support direct radiographic film exposures and is not intended for use in performing mammography.</p> | <p>Substantial equivalent</p> <p>The wording of the indications for use were updated. These changes do not raise new safety or effectiveness concerns with regard to the predicate device.</p> |
| Human<br>Factors       | <p>Only trained and instructed qualified personnel are allowed to operate the system.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p>Device labeling defines that only trained and instructed qualified personnel are allowed to operate the system.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>Substantial equivalence.</p> <p>The wording has changed, but does not have influence on the safety and effectiveness of the C-arm product.</p>                                              |
| <b>Standards</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                |

| Model     | Modified Ziehm Vision FD                                                                                                                                                                                                                                                                                                             | Predicate Ziehm Vision FD (K193230)                                                                                                                                                                                                                                                                            | Comparable Properties Substantial Equivalence Discussion                                                                                                               |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Standards | <ul style="list-style-type: none"> <li>• IEC 60601-1:2006/AMD1:2013</li> <li>• IEC 60601-1-2:2014</li> <li>• IEC 60601-1-3:2008/AMD1:2013</li> <li>• IEC 60601-1-6:2010/AMD2:2021</li> <li>• IEC 60601-2-43:2010/AMD2:2020</li> <li>• IEC 60601-2-54:2009/AMD2:2019</li> <li>• IEC 60825-1:2007</li> <li>• ISO 14971:2019</li> </ul> | <ul style="list-style-type: none"> <li>• ANSI/AAMI ES60601-1:2012</li> <li>• IEC 60601-1-2:2014</li> <li>• IEC 60601-1-3:2008 + A1:2013</li> <li>• IEC 60601-1-6:2013</li> <li>• IEC 60601-2-43:2010</li> <li>• IEC 60601-2-54:2009 + A1:2015</li> <li>• IEC 60825-1:2007</li> <li>• ISO 14971:2007</li> </ul> | Applicable standards for the modified Ziehm Vision FD and the predicate Ziehm Vision FD (K193230) remain as before. Newer versions of the standards have been applied. |

Conclusion of Table above: The changes of the proposed modified device Ziehm Vision FD described in the table do not change the fundamental control mechanism, operating principle or intended use found on predicate device and supports substantially equivalents to the predicate device Ziehm Vision FD (K193230) in accordance with its labeling.

Safety and Performance: The proposed Ziehm Vision FD C-arm's potential radiation, mechanical, and electrical hazards are identified and analyzed as part of risk management, and controlled by meeting the applicable CDRH 21CFR subchapter J performance requirements, recognized and general consensus standards, designing and manufacturing under Ziehm Imaging GmbH Quality System, and system verification and validation testing ensure the device performs to the product specifications and its intended use. The adherence to these applicable regulations and certification to Recognized Consensus Standards that apply to this product provides the assurance of device safety and effectiveness.

Summary of Non-Clinical Test Data: Ziehm Vision FD is based on direct modifications to cleared predicate device Ziehm Vision FD (K193230).

The design of the modified Ziehm Vision FD was completed in accordance with Ziehm Imaging GmbH Quality Management System Design Controls, 21 CFR 820 and applicable standards. Verification and Validation testing were successfully conducted on the device in compliance with FDA requirements as stated in the following documentation.

Testing regarding electrical safety according to ANSI/AAMI ES60601-1 and regarding electromagnetic compatibility according to IEC 60601-1-2 was performed. The test results show compliance with both standards.

Testing according to Guidance's "Radio Frequency Wireless Technology in Medical Devices" and "Design Considerations and Premarket Submissions Recommendations for Interoperable Medical Devices" show, neither the wireless features nor the interoperable interfaces of the device affect the safety and effectiveness.

The performance testing confirmed that the modified Ziehm Vision FD complies with 21 CFR 1020.30-32 Federal Performance Standards for X-Ray Fluoroscopic equipment and with relevant safety standards such as IEC 60601-1-3, IEC 60601-2-43, IEC 60601-2-54.

Non-clinical image comparison with sets of images with the modified device and the predicate shows equivalence regarding image quality.

With regard to the flat panel detector (SSXI), documentation provided in this submission demonstrates compliance of the modified device Ziehm Vision FD to "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

Furthermore, an assessment regarding the low dose functionality of the modified Ziehm Vision FD shows the ability to reduce dose for certain applications.

Software testing was performed as required by "Content of Premarket Submissions for Device Software Functions". Cybersecurity remains exactly the same as in the predicate device.

Determination of Substantial Equivalence: The verification/validation activities successfully confirmed device requirements have been fulfilled, system functionality is consistent with the user needs, intended uses, and performs as designed, and raises no new questions regarding either safety or effectiveness.

Therefore, Ziehm Imaging GmbH believes the modified device Ziehm Vision FD C-arm image quality, safety and effectiveness supports a determination of substantial equivalence to the predicate device Ziehm Vision FD (K193230).

#### Compliance to FDA Guidance and Standards

21 CFR 1020.30-32 Federal Performance Standard for Diagnostic X-ray Systems.

#### General Standards / Regulations

MDSAP Medical Device Single Audit Program (MDSAP)

Regulation (EU) Annex IX Chapter I, Section 2 and 3 and Chapter III  
2017/745

EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes  
Date: 2016

#### Recognized Consensus Standards

- ANSI/AAMI ES60601-1: Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod)  
Date: 2012  
Conformance Standard #19-4
- IEC 60601-1-2: Medical Electrical Equipment, Part 1-2: General Requirements for Safety, Electromagnetic Compatibility  
Edition 4.0, Date: 2014-02  
Conformance Standard #19-8
- IEC 60601-1-3: Medical Electrical Equipment, Part 1-3: Radiation Protection in Diagnostic X-ray Equipment  
Edition 2.1, Date: 2013-04  
Conformance Standard #12-269
- IEC 60601-1-6: Medical Electrical Equipment, Part 1-6: Usability  
Edition 3.2, Date: 2020-07  
Conformance Standard #5-132
- IEC 60601-2-43: Medical electrical equipment, Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures  
Edition 2.2, Date: 2019-10  
Conformance Standard #12-239
- 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, Date: 2018-06  
Conformance Standard #12-317
- IEC 61304: Medical device software - Software life cycle processes  
Edition 1.1, Date 2015-06  
Conformance Standard #13-79
- IEC 60825-1: Safety of laser products, Equipment Safety, requirements, and user guide  
Edition 2.0, Date: 2007-03  
Conformance Standard #12-273
- ISO 14971: Medical devices - Application of risk management to medical devices  
Edition 3.0, Date: 2019-12  
Conformance Standard #5-40

Determination of Substantial Equivalence: Summary Bench Testing  
Verification and Validation including hazard mitigations executed resulted in demonstrated system met Design Input and user needs.  
The device was tested by the notified test laboratory resulting in device being certified compliant with ANSI/AAMI ES60601-1-1 series, including IEC

60601-2-54. Further device met all applicable sections of 21 CFR Subchapter J performance standards.

The modified Ziehm Vision FD development occurred under our design control processes, software development processes, and overall quality management system. They included but are not limited to,

- Risk Analysis
- Required reviews
- Design reviews
- Component testing
- Integration testing
- Performance testing
- Safety testing
- Product use testing

Performance bench testing included:

Non-clinical imaging and dose testing methods demonstrated the device capability to provide both reduced dose while maintaining image quality. Further in line with UCM089742- Premarket Assessment of Pediatric Medical Devices May 24, 2014 and UCM 302938- Pediatric Information for X-ray Imaging Device Premarket Notifications Nov 28, 2017. Non-clinical image and dose Lab testing, were employed. Anatomical phantoms were employed, image comparison sets taken were representative of both the adult and pediatric populations. A Radiologist performed an assessment of individual image sets. Radiologist conclusion, the image quality of the Ziehm Vision FD results in a comparable patient care to the reference device Ziehm Vision FD (K193230) and fulfils the requirements as stated by the intended use. Therefore, Ziehm Imaging GmbH believes the Ziehm Vision FD C-arm image quality, safety and effectiveness to be substantially equivalent to that of the predicate device Ziehm Vision FD (K193230).

Conclusion Ziehm Imaging GmbH considers the Ziehm Vision FD to be as safe, as effective, and performs substantially equivalent to the predicate device Ziehm Vision FD (K193230) in accordance with its labeling.