June 21, 2024

Epica International, Inc.
% Craig Glaiberman
Chief Medical Officer
1875 East Main St., Spark Warehouse 92, Dock 12 & 13
DUNCAN, SC 29334

Re: K233230
Trade/Device Name: See Factor CT3™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAK
Dated: May 21, 2024
Received: May 21, 2024

Dear Craig Glaiberman:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

Sincerely,

Lu Jiang

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233230

Device Name
See Factor CT3™

Indications for Use *(Describe)*
The See Factor CT3™ is a flat panel cone beam computed tomography X-ray imaging system that is indicated for acquiring images of the head, neck, and limbs in all adult patients. It can also acquire portions of the thorax, spine, and pelvic bones with high x-ray attenuation such as bony structures in supine body parts no wider than 60cm. The device has a 62.5cm gantry bore with a 30cm field of view that can provide 2D and 3D images for all of the stated anatomical areas for both intra-operative and clinical use. The device is also capable of acquiring digital radiography and fluoroscopy images of the anatomical areas identified above.

The device is to be operated by licensed and credentialed medical professionals such as physicians, and radiology technicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Epica International, Inc.'s See Factor CT3™

K233230

Submitter

Epica International, Inc.
19810 Asheville Hwy
Landrum, SC 29356
Phone: +1 (916) 850-5866
Contact Person: Craig Glaiberman, MD, Chief Medical Officer

Date Prepared: June 21, 2024

Name of Device: See Factor CT3™

Common or Usual Name: Image-intensified fluoroscopic x-ray system

Classification Name: 21 CFR 892.1650

Regulatory Class: 2

Product Code: OWB, JAK

Predicate Device: Siemens Artis zeego (K181407)

Device Description

The See Factor CT3™ consists of a Diagnostic CBCT (Cone Beam Computed Tomography) device that integrates High-Definition Computed Tomography (HDCT) for obtaining High Resolution 3D Volume with 2D High Resolution Scouting, through Dynamic Scouting and Single Pulse Modality. Flat panel detector technology allows for multimodality utilization for computed tomography, digital radiography, and fluoroscopy. The gantry of the device is mounted to a battery powered mobile platform that allows use in various clinical settings such as an imaging center, a hospital, or an operating room where adequate radiation shielding is installed. Stray radiation mapping demonstrates no significant difference from the predicate See Factor CT3. The energy source and methodology for obtaining diagnostic CT images utilized by the See Factor CT3™ remains the same as its predicate device. No part of the See Factor CT3™ is intended to come into contact with patients during typical scans that take less than 20 minutes.

Intended Use / Indications for Use

> The See Factor CT3™ is a flat panel cone beam computed tomography X-ray imaging system that is indicated for acquiring images of the head, neck, and limbs in adult patients. It can also acquire images of portions of the thorax, spine, and pelvic bones with high x-ray attenuation such as bony structures in supine body parts no wider than 60cm. The device has a 62.5cm gantry bore with a 30cm field of view that can provide 2D and 3D images for all of the stated anatomical areas for both intra-operative and clinical use. The device is also capable of acquiring digital radiography and fluoroscopy images of the anatomical areas identified above.

The device is operated and used by physicians, x-ray technologists, and other legally qualified professionals.

Summary of Technological Characteristics

Computed tomography is the technological principle for both the subject and predicate device. Subject and predicate device are cone beam x-ray imaging systems that acquire diagnostic two- and three-dimensional images in DICOM format. At a high level, the subject and predicate devices are based on the following same technological elements:

- Subject and predicate devices have the same energy source for x-ray production, similar flat panel detectors, are DICOM compatible, and are both mobile or stationary.

The following technological differences exist between the subject and predicate devices:

- The See Factor CT3™ has the additional ability to obtain digital radiography and fluoroscopic images in DICOM format.

- The gantry of the See Factor CT3™ also has the capability to index over the patient providing a longer scan length. It also has higher resolution and isotropic voxels without interpolation.

- The subject See Factor CT3™ includes a drive system to aid in moving of the system.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the See Factor CT3™ system. The system complies with standards IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-43, IEC 60601-2-44, IEC 60601-2-54, for safety, and IEC 60601-1-2 for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

Bench Testing
Performance testing as outlined in *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices* Section VI have been performed to demonstrate adequate device performance. Additionally, bench testing for 3D imaging was conducted and 3D clinical sample images were obtained to support the performance of the CBCT modality.

In all instances, the See Factor CT3™ functioned as intended.

Conclusions

The See Factor CT3™ is as safe and effective compared to its predicate. The See Factor CT3™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended

diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the See Factor CT3™ and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the See Factor CT3™ is as safe and effective as the predicate device. Thus, the See Factor CT3™ is substantially equivalent.

A table comparing the key features of the subject and predicate devices is provided below.

	See Factor CT3 Proposed Device	Siemens Artis zeego (K181407) primary predicate device	Comment
Type of Device	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	
FDA Product Code	OWB, JAK	OWB, IZI, JAA, JAK	
FDA Regulation	21 CFR 892.1650	21 CFR 892.1650	
Device Class	Class II	Class II	
Indications for Use	The See Factor CT3™ is a flat panel cone beam computed tomography X-ray imaging system that is indicated for acquiring images of the head, neck, and limbs in adult patients. It can also acquire images of portions of the thorax, spine, and pelvic bones with high x-ray attenuation such as bony structures in supine body parts no wider than 60cm. The device has a 62.5cm gantry bore with a 30cm field of view that can provide 2D and 3D images for all of the stated anatomical areas for both intra-operative and clinical use. The device is also capable of acquiring digital radiography and fluoroscopy images of the anatomical areas identified above. The device is operated and used by physicians, x-ray technologists, and other legally qualified professionals.	Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the Artis family include cardiac angiography, neuro-angiography, general angiography, rotational angiography; multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities. Additional procedures that can be performed include angiography in the operating room, image-guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery, and interventions. Artis can also support the acquisition of position triggered imaging for spatial data synthesis.	Substantially equivalent. Both the subject and proposed predicate device provide fluoroscopic imaging and CT capabilities (both offer software reconstruction methods of x-ray images into 2D and 3D image formats).

		The Artis systems include also the software option DynaCT with following IFU: DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format. DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures, and treatment follow-up.	
Intended Use Environment	Imaging center, a hospital, or an operating room where adequate radiation shielding is installed.	Imaging center, a hospital, or an operating room where adequate radiation shielding is installed.	Same
Patient population	Adults (>18 years old)	Adults, pediatrics, obese patients	Predicate has expanded population indications compared to subject device. However this difference does not raise different questions of safety or effectiveness.
Imaging Modality	• CT • Fluoroscopy • Digital radiography	• Angiography • Whole body radiographic/fluoroscopic procedures • DynaCT • Angio-CT configuration (SOMATOM Family Sliding Gantry)	Substantially similar. The subject device offers a subset of imaging modalities similar to those of the predicate device. However this difference does not raise different questions of safety or effectiveness.
Patient Diagnostic	Yes	Yes	Same
Intraoperative Use	Yes	Yes	Same
Set-Up	• Fixed placement	• Fixed placement • Single or biplane	Similar
Mobile	Yes	No	Different. However, this difference does not raise different questions in terms of intended use, safety or effectiveness of the device as demonstrated by performance testing.
Gantry Bore Size	Circular bore maximum width of 62,5 cm	C-arm maximum depth 80cm	Substantially similar in configuration of source and detector position that does

			not raise different questions of safety or effectiveness.
Power supply	230 VAC 60/50 Hz, 5000VA (max)	N/A – information not available	Same
DAP	Yes	Yes	Same
MAR	Yes	Yes	Same
MIP	Yes	Yes	Same

	See Factor CT3 Proposed Device	Siemens Artis zeego (K181407) primary predicate device	Comment
Type of Device	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Same
FDA Product Code	OWB, JAK	OWB, IZI, JAA, JAK	Similar for fluoroscopic functionality of proposed device
FDA Regulation	21 CFR 892.1650	21 CFR 892.1650	Same
Device Class	Class II	Class II	Same

Indications for Use	The See Factor CT3™ is a flat panel cone beam computed tomography X-ray imaging system that is indicated for acquiring images of the head, neck, and limbs in adult patients. It can also acquire images of portions of the thorax, spine, and pelvic bones with high x-ray attenuation such as bony structures in supine body parts no wider than 60cm. The device has a 62.5cm gantry bore with a 30cm field of view that can provide 2D and 3D images for all of the stated anatomical areas for both intra-operative and clinical use. The device is also capable of acquiring digital radiography and fluoroscopy images of the anatomical areas identified above. The device is operated and used by physicians, x-ray technologistsand other legally qualified professionals.	Artis is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the Artis family include cardiac angiography, neuro-angiography, general angiography, rotational angiography; multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities. Additional procedures that can be performed include angiography in the operating room, image-guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery, and interventions. Artis can also support the acquisition of position triggered imaging for spatial data synthesis. The Artis systems include also the software option DynaCT with following IFU: DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format. DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional	Substantially equivalent. Both the subject and proposed predicate device provide fluoroscopic imaging and CT capabilities (both offer software reconstruction methods of x-ray images into 2D and 3D image formats).

		procedures, and treatment follow-up.	