June 20, 2023

Acrew Imaging, Inc.
% Yolanda Smith
Consultant
Yolanda Smith
1468 Harwell Ave.
CROFTON, MD 21114

Re: K222998
Trade/Device Name: F3
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: September 22, 2022
Received: September 28, 2022

Dear Yolanda Smith:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222998

Device Name
F3

Indications for Use *(Describe)*
F3 provides image guidance by overlaying a previously constructed preoperative vessel anatomy, from a previously acquired contrast-enhanced, diagnostic CT scan, onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices.

F3 is intended to assist fluoroscopy-guided endovascular procedures in the thorax. Suitable procedures include endovascular aortic aneurysm repair (AAA and mid-distal TAA) and angioplasty.

F3 i not intended for use in the X-Ray guided procedures in the liver, kidneys or pelvic organs.

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 K222998

Submitter:	Acrew Imaging, Inc.
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	College Park, MD 20742
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	CEO
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Email:	will@acrewimaging.com

Summary Preparation Date: September 22, 2022

Trade Name:	F3
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Common Name:	Image-Intensified Fluoroscopic X-Ray System
Regulation Number:	21 CFR 892.1650
Product Code:	OWB
Device Class:	Class II
Classification Panel:	Radiology

Primary Predicate Device:	K160088 Cydar EV
Regulation number:	21 CFR 892.1650
Product Code:	OWB
Device Class:	Class II

Device Description:

The purpose of F3 is to assist the user with the visual evaluation, comparison, and merging of information between anatomical and functional images from a single patient. The user needs to take into consideration the product's limitations and accuracy when

integrating the information from the registration results for final interpretation. F3 does not replace the usual procedures for visual comparison of datasets by a user. Fusion images are intended to provide additional information to a user's existing workflow for patient evaluation.

F3 offers:

- Visualization of multi-modality image data
- Automatic registration
- Import of DICOM data
- Capture of fluoroscopic image frames

Input and output

- Receive DICOM data from a network
- Reading DICOM data
- Fluoroscopic image frames

Indications for Use

F3 provides image guidance by overlaying a previously constructed preoperative vessel anatomy, from a previously acquired contrast-enhanced, diagnostic CT scan, onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices.

F3 is intended to assist fluoroscopy-guided endovascular procedures in the thorax. Suitable procedures include endovascular aortic aneurysm repair (AAA and mid-distal TAA) and angioplasty.

F3 is not intended for use in the X-ray guided procedures in the liver, kidneys or pelvic organs.

Predicate Product Comparison

Comments	Acrew	Cydar	Comments
510(k) Number		K160088	
Product Code	OWB	OWB	Same
Regulation Number	§892.1650	§892.1650	Same
Regulation Name	Image-Intensified Fluoroscopic X-Ray	Image-Intensified Fluoroscopic X-Ray	Same

Comments	Acrew	Cydar	Comments
	System	System	
Intended Use	Display of combined live 2D Xray fluoroscopy and 3D anatomy for image guidance during surgery procedures in the lower thorax.	Display of combined live 2D Xray fluoroscopy and 3D anatomy for image guidance during surgery procedures in the lower thorax, abdomen and pelvis..	Our product has not been evaluated for the use in abdomen and pelvis, so our intended use in the lower thorax is a subset of the predicate.
3-D Imaging	Pre-operative	Pre-operative	Same
X-Ray Fluoroscopy	Live	Live	Same
Construction	Software Product	Software Product	Same
Host Computer	Container suitable for running on a local computer or the cloud.	Separate interventional tools workstation	Our software runs in a container allowing it to be used on a local computer or in the cloud.
Registration Overview	2D-3D registration is achieved by machine vision tracking of vertebral anatomy combined with iterative intensity based similarity.	2D-3D registration is achieved by machine vision tracking of vertebral anatomy	To increase the robustness of the registration F# utilize both computer vision and an intensity based registration engine to find a 2D-3D registration result.
Registration Target	Anatomy present	Vertebral anatomy	Mutual information will use vertebral anatomy to guide registration, but will also utilize other structures present in both the CT and the fluoroscopic image to enhance

Comments	Acrew	Cydar	Comments
			the accuracy and robustness of the registration.
Patient Contacting	No	No	Same
Energy emitted or absorbed	No	No	Same
Dynamic update on C-arm / table motion	Automatic	Automatic	Same
Dynamic update on patient motion	Automatic	Automatic	Same
Anatomical Location	Vascular anatomy of the chest, abdomen and pelvis.	Vascular anatomy of the chest, abdomen and pelvis.	Same
Ability to store roadmaps	No	Yes	F3 is a visualization aid, not intended to support planning such as roadmaps.
Ability to store snapshots	Yes	Yes	Same
Non-clinical Performance Data			
IEC 62304	Applied	Applied	Same
IEC 62366	Applied	Applied	Same
ISO 14971	Applied	Applied	Same
NEMA PS 3.1-3.20 DICOM			

Discussion of Technological Differences

Indications for Use statement - The salient use difference between F3 and Cydar EV is F3 lacks a tool for constructing 3D vessel anatomy. Instead, users must create their own contours using other tools and then export them to F3. Once transferred to F3, the use of the tools is similar providing the overlay of the provided structures using the original CT used to create the structure. The lack of tool for constructing 3D vessel anatomy raises no new issue of safety and effectiveness.

Host computer – F3 software runs in a container allowing it to be used on a local computer or in the cloud, whereas the Cydar EV uses separate interventional tools workstation. The differences in host computers raises no new issue of safety and effectiveness.

Registration Overview - To increase the robustness of the registration, F3 utilizes both computer vision and an intensity based registration engine to find a 2D-3D registration result. The Cydar EV 2D-3D registration is achieved by machine vision tracking of vertebral anatomy. This difference raises the possibility of different effectiveness. We performed a variety of controlled experiments on phantom and clinical data to demonstrate that it performs as well or better than our predicate device and is comparable to experts. Based on this testing, we conclude that F3 is as safe and effective as our predicate device.

Registration Target – The F3 uses anatomy present and the Cydar EV uses vertebral anatomy. F3's Mutual information will use vertebral anatomy to guide registration but will also utilize other structures present in both the CT and the fluoroscopic image to enhance the accuracy and robustness of the registration. This difference raises the possibility of different effectiveness. We performed a variety of controlled experiments on phantom and clinical data to demonstrate that it performs as well or better than our predicate device and is comparable to experts. Based on this testing, we conclude F3 is as safe and effective as our predicate device.

Ability to store roadmaps - F3 is a visualization aid, not intended to support planning roadmaps. This issue raises no new issues of safety and effectiveness.

Nonclinical Performance Testing

Standards used:

- IEC 62304:2006 Medical Device software – Software life cycle processes
- IEC 62366: Edition 1.0 2015-02 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 14971: Third Edition 2019 medical device – Application of risk management to medical devices

Summary of Nonclinical Performance Testing

We performed our test of clinical acceptance based on clinical standards. For our evaluation with phantom data we utilized an thoracic phantom designed to provide

realistic arms abducted, thoracic imaging for CT and plain X-ray. For our evaluation with clinical data, 20 cases were utilized that were collected retrospectively over a 2 year period. Qualifying cases were those in which a fluoroscopic procedure had been done with the appropriate F3 setup criteria (i.e. AP fluoroscopic video of the thorax and a thoracic CT in which the field of view of axial slices did not crop any part of the body). The resulting selected cases ranged from 29 to 71 years old, with a mean age of 56.3 years and a standard deviation of 11.9. 8 cases were female.

We demonstrated for both rigid 6 parameter registration and for our dynamic panning that (1) our solution produces similar target registration error (TRE) to our predicate device on a thoracic phantom, (2) our solution produces clinically acceptable accuracy as defined by our predicate device as 3mm on clinical thoracic images that have been captured from an F3 configured setup, and (3) that our solution creates results that are preferred qualitatively by a group of board certified radiologists.

Clinical Studies

No clinical studies were done.

Conclusion:

F3 is similar to the predicate device but contains fewer features. These feature adjustments have been made in the interest of simplifying the workflow for users. From a user's point of view, the largest change is the lack of segmentation integrated in the tool. There are a number of reasons for this, but the primary one is that many existing tools can already be used for segmentation and used as input to F3. By taking a segmented result and exporting to a label map in the same space as the reference CT used for registration, users have the flexibility to use their preferred existing tools to create images for fusion. Because segmentations do not relate to the quality of the registration in our engine as discussed below, this does not raise any new issues of safety and effectiveness.

Our registration engines differ as well, whereas the predicate is based explicitly on vertebral based landmarks, ours is an intensity-based registration engine. The approach of intensity-based image registration we have demonstrated on a variety of different image domains. In this work we tested it on hundreds of image pairs to demonstrate its accuracy relative to expert identified results. These results and the long history of intensity-based registration effectively mitigate any issues of safety and effectiveness associated with this difference in registration engine.

The lesser featured F3 is therefore substantially equivalent to those components of the predicate device.