September 27, 2019

Turner Imaging Systems, Inc.
% D. Clark Turner, Ph.D.
President and CEO
1119 South 1680 West
OREM UT 84058

Re: K190024
Trade/Device Name: Smart-C™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OXO, JAA
Dated: August 26, 2019
Received: August 28, 2019

Dear Dr. Turner:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190024

Device Name
Smart-C ™

Indications for Use *(Describe)*

The Smart-C is a mini C-arm X-ray system designed to provide physicians with real time general fluoroscopic visualization of adult and pediatric patients. It is intended to aid physicians and surgeons during diagnostic procedures, therapeutic treatment, or surgical procedures of the limbs, extremities, or shoulders including but not limited to, orthopedics and emergency medicine. The Smart-C is intended to be used on a table or other hard flat surface. It may also be used with the optional support stand.

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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Tab 5

510(k) Summary

Submission # K190024

Smart-C X-ray Imaging System
26 August 2019

Submitter:

Name: Turner Imaging Systems, Inc.
Address: 1119 S 1680 W
Orem, UT 84058

Official Correspondent: Clark Turner, Acting Director of Quality and Regulatory Affairs

Telephone No: 801-796-2951
Email: cturner@turnerinnovation.com

Proposed Device:

Trade Name:	Smart-C™
Common/Usual Name:	Fluoroscopic X-ray System, Mobile
Classification Name:	Image-intensified fluoroscopic x-ray system
Primary Product Code:	OXO
Secondary Product Code:	JAA
Regulatory Standard:	21CFR 892.1650

Predicate Device: Orthoscan Mobile DI Mini C-arm, 510(k) # K113708, manufactured by Orthoscan.

Common/Usual Name:	Fluoroscopic X-ray System, Mobile
Classification Name:	Image-intensified fluoroscopic x-ray system
Product Codes:	OXO and JAA
Regulatory Standard:	21CFR 892.1650

Description: The Smart-C is an ultra-portable, battery-powered, mobile fluoroscopic mini C-arm system. The main component is a mini C-arm that consists of a CMOS flat panel detector aligned with an X-ray source monoblock to be used for image acquisition. The system can be hand-transported for imaging at the point of care. The primary operator workstation is a tablet computer that receives the images from the C-arm via wireless transfer protocol. The system includes a wireless footswitch to initiate image acquisition, making the entire system cord-free during operation. It comes with 2 battery packs, a table-top battery charger, and a tablet docking station.

An optional Monitor Cart is provided as an accessory. The Smart-C monitor cart includes a 27" full-color touchscreen monitor, a keyboard for data entry, a printer for hard-copy of the x-ray images, and a battery charger for the Smart-C battery packs. The whole cart is battery-powered, to provide a completely cord-free user experience.

Intended Use: The Smart-C is a mini c-arm X-ray system designed to provide physicians with real time general fluoroscopic visualization of adult and pediatric patients. It is intended to aid

physicians and surgeons during diagnostic procedures, therapeutic treatment, or surgical procedures of the limbs, extremities, or shoulders including but not limited to, orthopedics and emergency medicine. The Smart-C is intended to be used on a table or other hard flat surface. It may also be used with the optional support stand.

Table 1. Comparison with predicate device:

Characteristic or Property	**Predicate Device OrthoScan Mobile DI, K113708**	**Turner Imaging Systems Smart-C**
Classification	Regulation number: 21 CFR 892.1650 Regulation name: Image-intensified Fluoroscopic x-ray system Regulatory Class: II Product Code: OXO and JAA	Regulation number: 21 CFR 892.1650 Regulation name: Image-intensified Fluoroscopic x-ray system Regulatory Class: II Product Code: OXO and JAA
Intended Use	The OrthoScan Mobile DI [1000-0005] is a mini c-arm X-ray system designed to provide the physician with general fluoroscopic visualization of the patient including, but not limited to, surgical orthopedic procedures and critical and emergency care procedures in hospital, emergency care, critical care, clinical, or physician office environments. The Mobile DI is capable of generating, processing, capturing, saving and transmitting fluoroscopic images of patient extremities for the purpose of diagnostic imaging. In addition, the portability of the OrthoScan Mobile DI provides for ease of use in athletic team venues, and military units.	The Smart-C is a mini C-arm X-ray system designed to provide physicians with real time general fluoroscopic visualization of adult and pediatric patients. It is intended to aid physicians and surgeons during diagnostic procedures, therapeutic treatment, or surgical procedures of the limbs, extremities, or shoulders including but not limited to, orthopedics and emergency medicine. The Smart-C is intended to be used on a table or other hard flat surface. It may also be used with the optional support stand.
Electrical:		
Power	Must be plugged in to AC Mains	C-arm: Rechargeable lithium ion battery; 22.2VDC; 3.5AHr Tablet: Rechargeable lithium ion battery; 14.8VDC; up to 3.7AHr Monitor Cart: Rechargeable Battery, LiFePO4, 24VDC, 40AHr, plug into AC mains to charge battery Footswitch: Alkaline AA Battery; 1.5VDC
X-ray Source	Fixed anode, beryllium window Focal spot: 0.05mm Voltage range: 40 to 78 kV Current range: 40 to 160 μA Exposure: Continuous Duty Cycle: Continuous	Fixed anode, tungsten filament Focal spot: 0.03-0.05mm Voltage range: 40 to 80 kV Current range: 65 to 370 μA Exposure: Pulsed, 10FPS, 40ms per frame Duty cycle: 1 min. of fluoroscopy per 5 min.
Image Receptor	Type: CMOS Flat Panel	Type: CMOS Flat Panel

Characteristic or Property	Predicate Device OrthoScan Mobile DI, K113708	Turner Imaging Systems Smart-C
	Scintillator: Full Field: 15cm x 12cm Limited Field: 11cm x 8cm Pixel Size: 75 microns Array Size: 1.5k x 2k	Scintillator: Cesium Iodide Full Field: 15cm x 15cm Limited Field: 10cm dia. circle Pixel Size: 99 microns Array Size: 1.5k x 1.5k
Electrical Safety and EMI Standards	ANSI/AAMI std IEC60601-1 IEC60601-1-2	ANSI/AAMI std IEC60601-1 IEC60601-1-2
Mechanical/Physical:		
C-arm Physical Dimensions	C-arm: Inside depth: 23 cm (9 in) Free space: 35 cm (13.8 in) Height: 64 cm (25 in) Width: 29 cm (11.4 in) Outside depth: 49 cm (19.2 in)	C-arm: Inside depth: 31 cm (12.2 in) Free space: 34 cm (13.5 in) Height: 53 cm (21 in) Width: 20 cm (8 in) Outside depth: 46 cm (18 in)
Field of view	Normal mode: 15 cm x 12 cm Magnification mode: 11 cm x 8 cm	Primary collimation: 15 cm x 15 cm Secondary collimation: 10 cm diameter
Source to Detector distance (SDD)	45 cm	45 cm
Minimum Source to Skin Distance (SSD)	10 cm, 19 cm with spacer cone	10 cm, 20 cm with head extension
Weight	C-arm and power supply: 19.5 kg (43 lb.)	C-arm + battery: 7.3 kg (16 lb.) Tablet: 1.5 kg (3 lb.)
Imaging, Display, and Software:		
Monitor	20.1 inch monochrome LCD	Tablet: 13” full color touchscreen LCD with 1920 x 1080 resolution Monitor on Accessory Stand: 27” full color touchscreen LCD monitor with 1920 x 1080 resolution
Image Transfer	Wired	Wireless image transfer: IEEE 802.11AC with WPA2 encryption, 5GHz band, 80MHz bandwidth, MAC Address filtering and restricted to a single IP address. Beacon type handshake to verify communication every 100-200 msec.
Data Standard	DICOM	DICOM
Image Storage	12,000 images	80,000 images
Removable Data Storage	USB Port	USB Port
Hard Copy	Thermal Printer	Thermal Printer (optional)

Characteristic or Property	Predicate Device OrthoScan Mobile DI, K113708	Turner Imaging Systems Smart-C
Device		
Imaging Features	1 Main/2 Reference Windows Auto x-ray technique control Noise and motion reduction Auto/manual brightness and contrast control Negate Swap Save and autosave Last image hold Edge enhancement Zoom & Pan Image rotation Image flip/invert Cine	1 Main/1 Reference Window Auto x-ray technique control Noise and motion reduction Auto/manual brightness and contrast control Negate Swap Save and autosave Last image hold Edge enhancement Zoom & pan Image rotation Image flip/invert Automatic Sequence Record Metal Detection
Support	Can be placed on a hard surface or optional cart mounted.	Place on a table or other hard flat surface, or optional cart mounted.
Software	Windows operating system and Windows-like user interface.	Windows operating system with touchscreen user interface.
PACS Connectivity	Wireless	Wireless
X-Ray Performance		
Performance Standards	21CFR1020.30 21CFR1020.32 IEC60601-1-3 IEC60601-2-28 IEC60601-2-54	21CFR1020.30 21CFR1020.32 IEC60601-1-3 IEC60601-2-28 IEC60601-2-54

Discussion: The Smart-C and the Mobile DI both use the same fundamental scientific technology of generating fluoroscopic x-ray images using an x-ray source monoblock and flat-panel x-ray imaging detector in a fixed C-arm configuration. The mechanical arrangement between these components is almost identical. One difference is the main power source being a Li-ion battery pack in the Smart-C and standard mains power supply for the Mobile DI. The safety and efficacy considerations of battery power for the Smart-C are considered and mitigated through the Risk Analysis and design mitigations.

A significant difference between the 2 devices is the use of a standard computer and imaging monitor for the Mobile DI, and the use of a Tablet Computer with integrated touchscreen display as the primary workstation for the Smart-C. To evaluate the substantial equivalence of the tablet computer/display with a standard imaging monitor, we referred to the FDA Guidance Display Devices for Diagnostic Radiology. In addition to the display data, a Qualified Expert Evaluation of the diagnostic ability of the tablet display device was performed by 2 independent board-certified physicians. The conclusion of the expert evaluators is that the image quality of the tablet is diagnostic in all presented cases, and thus substantially equivalent to a standard surgical monitor for the intended use of the Smart-C device.

Another significant difference between the units is that the Smart-C uses WiFi technology to wirelessly transfer the images from the x-ray detector to the Tablet computer for display and processing. This allows the display device to be positioned independently of the Smart-C, and within the physicians preferred field of view. This improves the workflow and ease of imaging. FDA guidance documents used in the development of the device include Radio Frequency Wireless Technology in Medical Devices, and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Summary Reports were prepared to show how the Smart-C complies with these guidance documents.

Summary Bench Testing

A Qualified Expert Evaluation of the image quality of the Smart-C was performed by independent physicians utilizing images obtained from anthropomorphic phantoms. An additional Image Quality Performance test was completed using image quality phantoms for contrast and spatial resolution. Dynamic image resolution was assessed using rotation of a phantom with 2 lead dots.

In addition to the image quality bench studies, system verification and validation testing including hazard mitigation has been performed to demonstrate the Smart-C system meets design input and user needs.

The Smart-C system has been tested to show compliance with the applicable IEC series of x-ray performance standards, including IEC60601-2-54. It also meets all applicable 21CFR Subchapter J performance standards.

Summary Clinical Testing

The clinical utility of the Smart-C was demonstrated by performing a Clinical Imaging Evaluation. Cadaver subjects were chosen to represent the range of extremity imaging, including shoulders. To represent a range of imaging conditions the testing was performed in both standard fluoro and in low-dose mode. Image enhancement algorithms like recursive filtering and edge enhancement were evaluated, and suitable conditions determined for their use. Patient positioning considerations for adult patients were considered in a separate usability study.

To address the special needs of neonatal and infant patients, a Pediatric Imaging Usability Evaluation was performed. This included the additional consideration of patient positioning for these very small size subjects. The Smart-C is not indicated for whole-body imaging of pediatric patients, so this study was limited to extremity positioning.

Based on physician feedback, the clinical images obtained with the Smart-C were at least as good as the predicate device. There were no new concerns regarding patient positioning, including for neonatal and infant patients.

Conclusion: The Smart-C and the predicate device both have the same intended use to provide physicians with real-time fluoroscopic visualization of anatomy of extremities. They meet the same recognized performance and safety standards, and to conform to FDA guidance regarding solid-state x-ray imaging systems. The designs are based on the same modern technologies using a compact monoblock x-ray generator and flat-panel x-ray

detector, operating at similar power levels. Differences in technological characteristics (battery power, wireless image transfer, tablet display, and wireless footswitch) have been evaluated for safety hazards utilizing risk management activities and risk analysis. The design mitigations were successfully tested during verification and validation. The Smart-C has been evaluated by numerous physicians and surgeons for image quality and usability on anthropomorphic phantoms, image quality phantoms, and cadaver subjects in clinical settings. They determined that it performs at least as well as the predicate device, and that it is efficacious for the intended uses.

We conclude that the Smart-C is of comparable type and substantially equivalent to the predicate device Orthoscan Mobile DI (K113708) and is safe and effective for its intended use.