Surround Medical Systems
% Ms. Elizabeth Sullivan
VP, Engineering
175 Southport Dr, Suite 900
MORRISVILLE NC 27560

July 28, 2021

Re: K211014
Trade/Device Name: Portray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: June 25, 2021
Received: June 28, 2021

Dear Ms. Sullivan:

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,

, for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211014

Device Name
Portray System

Indications for Use *(Describe)*
The Portray System is an extraoral X-ray source (intraoral X-ray detection) dental X-ray system for producing diagnostic dental radiographs of the teeth, jaw, and other oral structures. The system provides 2D imaging for diagnostic purposes and 3D imaging as an adjunctive tool.

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

Date Summary Prepared: April 2, 2021

510(k) Owner: Surround Medical Systems

Contact Person: Elizabeth Sullivan
VP Engineering
175 Southport Drive
Suite 900
Morrisville, NC 27560
919-424-4900

Device Name:

Device Name:	Portray System
Trade Name:	Portray System
Common Name:	Extraoral source dental x-ray system
Regulation:	21 CFR 872.1800, Extraoral source X-ray system
Class:	II
Product Code:	EHD

Predicate Device(s): RiX70 DC, K182206

Device Description: The Portray System, an extraoral X-ray source (intraoral X-ray detection) dental X-ray system, is a nanotechnology-based 2D and 3D extraoral imaging system offering high resolution X-ray image quality and diagnostic accuracy. The 3D image provides a layer-by-layer virtual dissection of the oral cavity when viewed as Tomosynthesis. Alternatively, when viewed as Synthetic 2D, the image provides a rotatable representation of a 2D image taken from the same point in space. 3D images are to be used only as an adjunct to 2D image analysis.

The Portray System is comprised of the following components:

- Computer
- User Interface Software
- High voltage Electronics
- Wall-mount
- Articulating Arm
- X-ray Source Array (Tube)
- X-ray Shielding
- X-ray Collimator
- Detector Holder
- Intraoral X-ray Detector

The Portray Detector Holder and off-the-shelf detector sleeve are accessories to the Portray System and the sole patient contacting components.

The Portray system will be available in a single, wall-mounted configuration.

The Portray system software will support interoperability with electronic patient records and storage of X-ray images in a persistent database located on a Local Area Network (LAN).

Statement of Intended Use: The Portray System is an extraoral X-ray source (intraoral X-ray detection) dental X-ray system for producing diagnostic dental radiographs of the teeth, jaw, and other oral structures. The system provides 2D imaging for diagnostic purposes and 3D imaging as an adjunctive tool.

Comparison of Technological Characteristics with Predicate Devices:

Device	**Proposed Device**	**Predicate device**
	Intraoral Tomosynthesis System (Portray System)	**RiX70 DC K182206**
Regulation Number / Product Code	21 CFR 872.1800 / EHD	21 CFR 872.1800 / EHD
	Conclusion – Substantially equivalent. Both the proposed and predicate device fall under the same regulation and product code.	
Intended Use	The Portray System is an extraoral X-ray source (intraoral X-ray detection) dental X-ray system for producing diagnostic dental radiographs of the teeth, jaw, and other oral structures. The system provides 2D imaging for diagnostic purposes and 3D imaging as an adjunctive tool.	The RiX70 DC is designed for the acquisition of intraoral images of the teeth, jaw and the mouth structure for diagnostic purposes.
	Conclusion – Substantially equivalent. Both the proposed and predicate device are intended for acquisition of intraoral images using an extraoral x-ray source. The intended use statement for the predicate does not specifically indicate that the x-ray source is extraoral, however the associated regulation and FDA product code is specific to extraoral x-ray devices. The proposed Portray System includes the ability to view the 2D images in a 3D format. This imaging capability is an adjunctive tool only and does not raise new questions of safety or effectiveness.	
Target Anatomical Sites	Oral Cavity	Oral Cavity
	Conclusion – Substantially equivalent. Both the proposed and predicate device target the oral cavity.	
Principle of use	X-ray tube	X-ray tube
	Conclusion – Substantially equivalent. Both the proposed and predicate device use X-ray tubes.	
Installation Configuration	Wall-mounted	Wall-mounted standard version and Stand mobile version
	Conclusion – Substantially equivalent. Both the proposed and predicate device are installed on a wall. The predicate offers an additional stand-mobile version in addition to the wall mounted version. However, this difference has no impact on substantial equivalence.	

Comparison of Technological Characteristics with Predicate Devices:

Device	**Proposed Device**	**Predicate device**
	Intraoral Tomosynthesis System (Portray System)	**RiX70 DC K182206**
X-ray emission control	Wired control	Wired Control
	Conclusion – Substantially equivalent. Both the proposed and predicate device have wired control of x-ray emission.	
HV generator	High frequency DC generation, constant output potential	High frequency DC generation, constant output potential
	Conclusion – Substantially equivalent. Both the proposed and predicate device generate the high voltage DC output with high frequency converters and have constant potential outputs.	
Cathode Material	Carbon Nanotube (CNT)	Heated Tungsten Filament
	Conclusion – Substantially equivalent. The cathodes of the Portray device and the predicate device use different materials to achieve an electron source within the X-ray Tube. The Portray device uses energized CNTs as a cold cathode, while the predicate device uses a heated filament. While the mechanism by which the electrons are generated differ, the resulting X-ray tubes are capable of producing radiation which meets safety and efficacy standards of 60601-2-65 and 61223-3-4. Therefore, the differing cathode material has no impact on safety or efficacy.	
Anode Material	Tungsten	Tungsten
	Conclusion – Substantially equivalent. The anode material of both the proposed and predicate device is Tungsten.	
Tube Voltage	60 kV, 70 kV	60, 65, 70 kV
	Conclusion – Substantially equivalent. Both the proposed and predicate device have tube voltages of 60 kV and 70 kV. The difference of Portray not including a tube voltage of 65 kV does not impact substantial equivalence.	
Tube Current	7 mA	7 mA
	Conclusion – Substantially equivalent. Both the proposed and predicate device have a tube current of 7 mA.	
Exposure Time	0.04 - 0.25 sec (2D) 0.063 – 1 sec (3D)	0.02 – 2 sec
	Conclusion – Substantially equivalent. Both the proposed and predicate device have an exposure time between 0.04 and 0.25 seconds. The exposure time for 3D images is also within the exposure time for the predicate's 2D image acquisition.	
X-ray tube Anode angle	12˚	16˚
	Conclusion – Substantially equivalent. Both the proposed and predicate device have an anode angle within the approximate anode angle range for most x-ray tubes. A smaller angle expects a larger focal spot size.	
Focal spot size	0.7	0.4
	Conclusion – Substantially equivalent. The focal spot size of the Portray device is larger than that of the predicate devices. The size of a focal spot has two implications in an X-ray system, namely that smaller focal spots generate more heat at the anode and produce superior resolution. By increasing the focal spot size, there are no new concerns relating to safety of the device because there is less heat produced at the focal spots. By increasing focal spot size, the spatial resolution of the Portray device is likely less than that of the predicates. However, the Portray device meets both internal requirements and requirements specified in IEC 61223-3-4 on image resolution. Therefore, the increased focal spot size has no impact on efficacy.	
Leakage radiation	< 0.25 mGy/h (@ 1 m)	< 0.25 mGy/h (@ 1 m)
	Conclusion – Substantially equivalent. Both the proposed and predicate device has the same leakage radiation.	

Comparison of Technological Characteristics with Predicate Devices:

Device	**Proposed Device**	**Predicate device**
	Intraoral Tomosynthesis System (Portray System)	**RiX70 DC K182206**
Focal film distance	Source to end of Cone Distance: 308 mm Source to Detector Distance: 400 mm	Standard round (fix): 200 mm (8”)
	Conclusion – Substantially equivalent. The focal film distance for Portray meets the requirements of IEC 60601-2-65 of at least 20 cm (200 mm). The dimensional differences between Portray and the predicates reflect a design choice and do not raise any questions of safety or efficacy.	
Dimensions of x-ray beam cone	Rectangular: 36.65mmx36.65mm	Short round (fix): Ø 60 mm Standard rectangular (removable): 45 x 35 mm
	Conclusion – Substantially equivalent. Portray is intended to only be used with the included electronic detector and utilizes a permanent beam limiting device to ensure that the dimensions of the x-ray beam are restricted to the active area of the detector in compliance with IEC 60601-2-65. The differences in the dimensions of the x-ray beam do not raise any questions of safety or efficacy.	
Exposure times control	Microprocessor controlled exposure times	Microprocessor controlled exposure times
	Conclusion – Substantially equivalent. Both the proposed and predicate device control exposure time via microprocessor.	
Exposure modes	Preset loading factors or manual mode	Preset loading factors or manual mode
	Conclusion – Substantially equivalent. Both the proposed and predicate device have preset loading factors as well as manual method of adjusting exposure modes.	
Selectable parameter	Patient type, anatomical position, 2D or 3D mode, X-ray Tube voltage, exposure time	Patient type, anatomical position, film type, X-ray Tube voltage, exposure time
	Conclusion – Substantially equivalent. Both the proposed and predicate device have the same selectable parameters, with two exceptions. The Portray system has a selectable mode. The 2D mode and adjunct 3D mode from the Portray System have exposure parameters contained within the predicate device’s exposure parameters, so this does not raise any questions of safety or efficacy. Film type is not selectable on the Portray System. However, this has no impact on substantial equivalence as the Portray System only supports digital detectors.	
Patient type	Adult and children older than 5	Adult and child
	Conclusion – Substantially equivalent. Both the proposed and predicate device may be used for adults and children. The predicate’s use on children includes those aged 2-5, while the Portray System does not recommend using on children younger than 5. The difference in patient type for the Portray System is because it is believed that children under the age of 5 are undergoing dental development such that Dental Professionals can see between their teeth, and the use of an X-ray system would not add any benefit. There are no reasons for exclusion of this group from a safety or effectiveness perspective- only to avoid unnecessary exposure to X-ray radiation.	
Film type	Digital sensor	Photo-stimulated plate or digital sensor
	Conclusion – Substantially equivalent. Both the proposed and predicate device use digital sensors to capture images.	

Comparison of Technological Characteristics with Predicate Devices:

Device	**Proposed Device**	**Predicate device**
	Intraoral Tomosynthesis System (Portray System)	**RiX70 DC K182206**
Image Type	2D and 3D	2D
	Conclusion – Substantially equivalent. Both the proposed and predicate device capture 2D images. The Portray Device can create a tomosynthesis reconstruction to create a 3D representation. The 3D presentation is adjunctive to 2D. A tomosynthesis reconstruction is a stack of multiple 2D images where each image is a slice of the object being imaged at a fixed incremental distance away from the detector.	
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 61223-3-4	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304
	Conclusion – Substantially equivalent. Both the proposed and predicate device comply to the same standards. The additional identified standard IEC 61223-3-4 is utilized for purposes of evaluating performance. There are no new technological characteristics which warrant the additional standard evaluation.	

Non-Clinical Performance Data: Non-clinical performance testing was performed to verify substantial equivalence to predicate devices. Testing included:

- Electrical Safety
- Electromagnetic Compatibility
- Human Factors
- Cybersecurity and Patient Information Protection
- Reliability and Accelerated Aging
- Software Verification and Validation
- Intended Use Validation
- Exit Field Dimensions
- Focal Spot Size
- Linearity and Coefficient of Variation of Air Kerma
- Line Pair Resolution
- Low Contrast Resolution

Assessment of Clinical Data: No clinical data was required to demonstrate substantial equivalence.

Overall Conclusions: Based on the indications for use, technological characteristics, and comparison to predicate device, the Portray System has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.