July 6, 2023

3Dio
℅ Mr. Douglas Hansen
President
1119 South 1680 West
OREM UT 84058

Re: K223780
Trade/Device Name: Lumos 3DX™
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: June 1, 2023
Received: June 5, 2023

Dear Mr. Hansen:

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
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223780

Device Name
Lumos 3DX ™

Indications for Use *(Describe)*
The Lumos 3DX ™ 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 3D imaging for diagnostic purposes via tomosynthesis. For use on adult patients only.

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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Lumos 3DX X-ray Imaging System
12 June 2023

Submitter:

Name: 3Dio, LLC.
Address: 1119 S 1680 W
Orem, UT 84058

Official Correspondent: Doug Hansen, CEO and President

Telephone No: 801-796-2951
Email: dhansen@3dteeth.com

Proposed Device:

Trade Name:	Lumos 3DX™
Class:	II
Common/Usual Name:	Dental X-ray System, Mobile
Classification Name:	Extraoral source x-ray system
Primary Product Code:	EHD
Regulatory Standard:	21CFR 872.1800

Predicate Device:

Manufacturer:	Surround Medical Systems
Trade Name:	Portray System
510(k):	K211014
Class:	II
Common/Usual Name:	Extraoral source x-ray system
Primary Product Code:	EHD
Regulatory Standard:	21CFR 872.1800

Description: The Lumos 3DX system is a 3D dental chairside X-ray system on a mobile stand that uses tomosynthesis (limited-angle tomography) to generate 3D images of the teeth and surrounding structures. A custom digital sensor is placed in the patient's mouth and multiple images are acquired around an arc of rotation and then fed into a 3D reconstruction algorithm.

The digital sensor provided with the system is specifically for use with the Lumos 3DX device. The sensor has a higher frame rate that enables the Lumos 3DX system to capture 30 images in a short period of time.

A server is provided as part of the Lumos 3DX system and wirelessly connects to one or more Lumos 3DX systems. After capturing images, the Lumos 3DX wirelessly transfers them to the server for reconstruction. This server can then be connected to the local network for access of the reconstructed data.

Indications for Use: The Lumos 3DX™ 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 3D imaging for diagnostic purposes via tomosynthesis. For use on adult patients only.

Table 1. Comparison with predicate device:

Characteristic or Property	**Surround Medical, Portray System, K211014**	**3Dio Lumos 3DX**
Classification	Regulation number: 21 CFR 872.1800 Regulation name: Extraoral source x-ray system Regulatory Class: II Product Code: EHD	Regulation number: 21 CFR 872.1800 Regulation name: Extraoral source x-ray system Regulatory Class: II Product Code: EHD
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 Lumos 3DX™ 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 3D imaging for diagnostic purposes via tomosynthesis. For use on adult patients only.
Target Anatomical Site	Oral Cavity	Oral Cavity
Principle of Use	X-ray tube	X-ray tube
Electrical:		
Power	Must be plugged in to AC Mains	Must be plugged in to AC Mains
X-ray Source	Anode: Tungsten Cathode: Carbon Nanotube Focal spot: 0.7mm Tube Voltage: 60 or 70 kV Current: 7 mA Exposure time: 0.6 Sec (2D & 3D) Tube Anode Angle: 12°	Anode: Tungsten Cathode: Tungsten Filament Focal spot: 0.4mm Tube Voltage range: 60 to 70 kV Current range: 3 mA to 7mA Exposure Time: 0.063 – 1.0 sec (3D) Tube Anode Angle: 12°
Leakage Radiation	< 0.25 mGy/h (@ 1 m)	< 0.25 mGy/h (@ 1 m)
Exposure Type	Multi-beam stationary	Single beam pulsed
Exposure Times	Microprocessor controlled exposure times	Microprocessor controlled exposure times
Exposure Modes	Preset loading factors or manual mode	Preset loading factors or manual mode
Selectable parameter	Patient type (adult/child), anatomical positions, 2D or 3D mode, x-ray tube voltage, exposure time	Anatomical positions, 3D mode, x-ray tube voltage & current
Image type	2D diagnostic and/or 3D adjunct	3D Diagnostic with 2D slices
Image data acquired	7 images	30 images
Detector	Digital Sensor Frame Rate: < 2 images per second Xray Sensitivity: Standard dental detector X-ray sensitivity	Custom #2 intra-oral digital sensor (19.5 µm x 19.5 µm pixel size) Frame Rate: ≥ 9.0 images per second Xray Sensitivity: High-sensitivity for low-dose rapid 3D data acquisition

Characteristic or Property	**Surround Medical, Portray System, K211014**	**3Dio Lumos 3DX**
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 61233-3-4 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 61223-3-4 IEC 62304 IEC 62366-1
Mechanical/Physical:		
Physical Dimensions	Head: Length: ~49 cm (~19 in) Width: ~20 cm (~8 in) Height: ~18 cm (~7 in) Arm: Vertical Reach: ±19.5” from neutral Horizontal Reach: 41.1” extension arm reach with 177° rotation. The articulating arm has 42.7” of additional extension with 205° of rotation.	X-Ray Head: Length: 34.5 cm (13.6 in) Width: 38.4 cm (15.1 in) Height: 31.8 cm (12.5 in) Arm: Vertical Reach: ±18” from neutral Horizontal Reach: The articulating arm has 40” of extension with 90° of rotation. Stand: Height with folded arm: 200 cm (78.7 in) Width of base: 54.0 cm (21.2 in) Length of base: 50.8 cm (20.0 in)
Source to Detector distance (SDD)	400 mm	313 mm
Minimum Source to Skin Distance (SSD)	308 mm	200 mm
Weight	112.5 lbs	117.0 lbs
Imaging, Display, and Software:		
Sensor Physical Dimensions	Exterior Size: 41.76 mm x 30.42 mm Imaging Size: 35.92 mm x 25.82 mm Pixel Size: 19.5 µm x 19.5 µm Image Resolution: 1324 x 1842	Exterior Size: 41.82 mm x 30.50 mm Imaging Size: 35.98 mm x 26.25 mm Pixel Size: 19.5 µm x 19.5 µm Image Resolution: 1346 x 1845
Sensor Technology	CMOS with Cesium Iodide Scintillator	CMOS with Cesium Iodide Scintillator
Dimensions of X-ray beam at Imaging Plate	36.6 mm x 33.6 mm Rectangle	63.6 mm x 59.7 mm Ellipse
Data Transfer Rate	<0.5 Frames/sec	≤ 10.2 Frames/sec

Characteristic or Property	Surround Medical, Portray System, K211014	3Dio Lumos 3DX
X-ray signal Gain (WRT standard)	1X	About 9X
X-ray emission control	Wired Control	Wired control
3D data acquisition time	6 sec (approximately)	3 sec (approximately)
3D slice thickness	0.5 mm fixed	Variable down to <0.1 mm
3D volume rendering	No	Yes
2D Image	Synthetic	2D Slices
Acquisition Geometry	Arc segment	360° Conical
Installation Configuration	Wall Mount	Mobile Stand
Software	Windows operating system and Windows-like user interface.	Windows operating system with touchscreen user interface.

Discussion: The Lumos 3DX system and the Portray System are both intra-oral x-ray systems that take multiple images and render a finished image for viewing. The systems view these images in slices that allow the dental professionals to see the teeth at various depths. The Portray system uses carbon nanotubes in its X-ray source that are positioned along an arc to get their seven shots from different angles. The Lumos 3DX uses a conventional X-ray Tube that pulses 30 times while rotating along a 360° circular path.

The Lumos 3DX and predicate device both allow for viewing slices, but the thickness is much smaller in the Lumos 3DX system which allows for a more detailed viewing process for the dental professional. In addition, because the Lumos 3DX takes images around a circle rather than along a single plane it provides more spatial information for reconstruction. The Portray System is a wall-mounted system while the Lumos 3DX system is on a stand, but both have articulating arms. In both systems, an alignment aid is used to hold the detector in the correct position relative to the x-ray source and that alignment aid is magnetically attached to the front of the nose cone.

In dental imaging Panoramic and Cone Beam CT systems are used to obtain 3D images of patient's oral structures. This is possible because the x-ray source and detector are external and rotate around the patient's head. These systems are large and expose the patient to a significant amount of radiation. The Lumos 3DX system is a smaller system that can take images of a more focused area using less radiation. Its portability also allows it to be used for unconscious patients while they lay in the chair rather than needing to move them to the x-ray device.

Bench and Radiation Safety

Testing Summary: An Image Quality Performance test was completed using image quality phantoms for spatial resolution, contrast, and noise. The 3D volume voxel size was also verified.

The effect of patient motion was evaluated to verify that typical movements induced by a patient during imaging do not significantly affect the system or the resulting 3D volume. The results of the patient motion studies justify the use of dental phantoms and cadaver subjects for the analysis of clinical image quality.

In addition to the image quality bench studies, system verification and validation testing including hazard mitigation has been performed to demonstrate the Lumos 3DX meets design input and user needs.

The Lumos 3DX has been tested to show compliance with the applicable IEC series of x-ray performance standards, including IEC60601-2-65. It also meets all applicable 21CFR Subchapter J performance standards including those for radiation safety, such as dosimetry, leakage, and stray radiation.

Clinical Image Quality

Testing Summary: The clinical utility of the Lumos 3DX was demonstrated by performing a Clinical Imaging Evaluation with dental professionals. Dental phantoms with human teeth and simulated bone as well as Cadaver subjects were selected to represent typical use cases for the Lumos 3DX. A number of 3D images were obtained for analysis and review.

Based on the evaluations made by the dental professionals, the images obtained with the Lumos 3DX were of diagnostic quality for clinical use.

Conclusion: Based on successful verification and validation testing, conformance to recognized performance standards and FDA guidance, and development under the 3Dio Quality Management System, we conclude that the Lumos 3DX Imaging System is substantially equivalent to the predicate device Surround Medical, Portray System (K211014) and is safe and effective for its intended use.