July 5, 2024

Lucas Lifecare
℅ Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K241305
Trade/Device Name: LifeRay™ Intraoral Handheld X-ray
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: April 30, 2024
Received: May 9, 2024

Dear Mr. Kim:

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)*
K241305

Device Name
LifeRay™ Intraoral Handheld X-ray

Indications for Use *(Describe)*

The Lucas Lifecare's Life Ray handheld is indicated for use only by a trained and qualified dentist or dental technicians for both adult and pediatric subjects for producing diagnostic dental images using various intraoral image sensors/receptors.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (K241305)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR 872.1800

Date 510(k)submitted: 05/01/2024.

1. **Submitter Information:**

Sumitter's Name	: Lucas Lifecare
Address	: 2302 Beloit Avenue, Janesville, Wisconsin 53546.
Contact Person	: Joseph Paul, CTO
Telephone Number	: 608-373-4301, 044 7549 996549, +91 95919-74913.
Email	: Joseph@lucaslifecare.com
Official Correspondent	: Dave Kim, MBA, MTech Group LLC
Address	: 7505 Fannin St. Suite 610, Houston, TX 77054
Tel	: 713-467-2607
Email	: davekim@mtechgroupllc.com

2. **Trade/ Proprietary Name:**

Trade/ Device Name	: LifeRay™ Intraoral Handheld X-ray
System Manufacturer Name	: Lucas Lifecare
Common Name	: Portable X-ray System
Regulation Name	: Extraoral Source X-ray System
Regulation Number	: 21 CFR 872.1800
Primary Product Code	: EHD
Classification Name	: Unit, X-ray, Extraoral with Timer
Regulatory Class	II
510K Review Panel	: Dental

3. **Legally Marketed Predicate Device Information: (K173319)**

Trade/ Device Name	: KaVo NOMAD Pro 2 Handheld X-ray System
Manufacturer Name	: Aribex
Common Name	: Portable X-ray System
Regulation Name	: Extraoral Source X-ray System
Regulation Number	: 21 CFR 872.1800
Primary Product Code	: EHD
Classification Name	: Unit, X-ray, Extraoral with Timer
Regulatory Class	II
510K Review Panel	: Dental

	LUCAS LifeRay™ Intra oral Handheld X-ray System	KaVo NOMAD Pro2 Handheld X-ray System (K173319)	Remarks
INDICATIONS FOR USE:	The Lucas Lifecare's LifeRay™ handheld is indicated for use only by a trained and qualified dentist or dental technicians for both adult and pediatric subjects for producing diagnostic dental images using various intraoral image sensors/receptors.	The KaVo NOMAD Pro 2 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoralimage receptors.	Equivalent
MECHANICAL:			
Size: Body (mm/inch)	12.8" L x 5.0" W x 11.3" H	11"L x 10.5"H x 5.5"W	Similar
Weight	5.3 lbs.	6.0 lbs.	Better
Source to skin distance	20 cm	21 cm	Equivalent
Cone diameter	6 cm	6 cm	Same
User Interface	Similar, plus several user-selectable preset times.		Equivalent
Backscatter radiation protection	6.75" dia. Pb-filled acrylic plastic scatter shield	6.75" dia. Pb-filled acrylic plastic scatter shield	Same
Exposure switch	Trigger located on handset	Trigger located on handset	Same
Tube head mounting	Handheld		Same
ELECTRICAL:			
Tube head	RADII™ KL11-0.4-70 Series	Cyprus PSOC CY8C29866	Equivalent
Energy Source	Rechargeable 21.6 V 3200 mAh Li-ion battery	Rechargeable 21.6 V DC Li-ion battery core pack	Equivalent/Better
Capacity	3.2 A-hr.	1.7 A-hr.	Equivalent/Better
Recharge capability	After 300 cycles or full drained	70% remaining capacity after 300 cycles	Equivalent

Exposure Time	0.01s -1.0s in 0.01s increments	0.02s – 1.0s in 0.01s increments	Equivalent/Better
mA	2.6 mA fixed	2.5 mA fixed	Equivalent/Better
kVp	Adjustable kVp 60,65,70	60 kVp fixed	Better
Electrical Safety Standards	IEC 60601-1:2006+A1:2013+ AC:2014 +A12:2014 +A2:2020	AAMI ES60601-:2005/(R)2012 And A1:2012	Same
EMI Standards	IEC60601-1-2 Ed. 4	IEC60601-1-2 Ed. 4	Same
X-RAY PERFORMANCE:			
Performance Standard	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-65, IEC60601-2-28	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-65	Better

4. **Description of Device:**

LifeRay™ is a battery-operated, handheld, dental X-ray device. LifeRay™ employs a 100 kHz high-frequency DC X-ray generator. This oil-cooled and shielded tube head is energized by a rechargeable lithium-ion battery pack. The battery is housed under the handle to enable portability. The battery gets charged when the device is docked into its cradle, which is powered through an AC- DC power supply. To focus exposure on the specified zone of the subject, and limit radiation leaking elsewhere out of the device, a shielded beam-limiting cone is engaged to the output of the tube head. This restricts the X-ray field to 60 mm diameter, compatible to dental image receptors. An additional transparent, circular backscatter shield is provided which shall be permanently mounted around the exit of the beam limiting cone to arrest radiation scattering back from the subject, so clinicians can perform in proximity. A wrist lanyard facilitates secure grip, and an inclination display aids in consistent repeatability of radiographs. LifeRay™ employs a fixed tube current of 2.6 mA, but has three selectable tube voltages: 60, 65, or 70 kVp. Exposure duration can be set between 10 ms to 1 s in steps of 10 ms. All these presets can be selected from the home screen of the display through a practical keypad to achieve the best radiograph results.

5. **Indications for Use:**

The Lucas Lifecare's LifeRay™ handheld is indicated for use only by a trained and qualified dentist or dental technicians for both adult and pediatric subjects for producing diagnostic dental images using various intraoral image sensors/receptors.

6. **Description of Substantial Equivalence:Technological Characteristics:**

Technological Characteristics:

LifeRay™ has similar design components and operating features as the predicate device, KaVo NOMAD Pro 2 Handheld X-ray System (K173319).

The handheld device features a main unit (tube head), rechargeable battery and charger. The main components of the tube head including X-ray tube, internal shielding and external backscatter shielding are like the predicate device. The functionality of the user interface is also like the predicate device.

The power is supplied by a rechargeable Lithium-Ion battery core pack built into a handset. The design for Liferay is equipped with a 21.6 VDC, 3.2 Ahr battery core pack compared to the predicate device (KaVo NOMAD Pro 2 Handheld X-ray System - K173319) design of 21.6 VDC, 1.7 Ahr. The LifeRay™ battery core pack is compliant with IEC 62133-2.

LifeRay™ is not capable of network connection and it does not contain other connected capabilities. LifeRay™ is not a cyber device and not subject to cybersecurity risks and threats per Section 524B.

Non-Clinical Test Data:

Testing was performed in accordance with the following international standards:

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION (Recognition No19-49)

IEC 60601-1-2 Edition 4.1 2020 Medical Electrical Equipment – Part 1-2: GeneralRequirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests

IEC 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (Recognition No: 19-19)

IEC 60601-1-3 Edition 2.1 2013-04 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: RadiationProtection in Diagnostic X-ray Equipment (Recognition No: 12-269)

IEC 60601-2-28 Edition 3.0 2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (Recognition No: 12-204)

IEC 60601-2-65 Edition 1.2 2021 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment (Recognition No: 12-340)

IEC 62133-2: Edition 1.0 2017: Lithium System (Recognition No: 19-33)

IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes (Recognition No: 13-79)

FDA Guidance Documents Utilized:

Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use, issued. December 24, 2008

Guidance for the Content of Premarket Submissions for Software Contained in MedicalDevices, issued June 14, 2023

Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 28,2017

Clinical Performance Data:

Clinical radiographic images using of LifeRay™ and the predicate device have been reviewed and compared to determine the substantial equivalence. Both intraoral X-ray systems generate adequate anatomical details using an intra oral sensor. Difference in edge definition and grayscale of bony structures for both images were negligible. Both intraoral X-ray systems generate sufficient X-ray levels to obtain acceptable edge definition and grayscale of bony and soft tissue images.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the LifeRay™ Handheld Dental X-Ray is deemed to be substantially equivalent to the predicate device.