September 1, 2023

Changzhou Sifary Medical Technology Co., Ltd.
℅ Mr. Lee W. Strong
Regulatory Dept Manager
510k FDA Inc.
156 E. Granada Blvd.
ORMOND BEACH FL 32176

Re: K232068
Trade/Device Name: HyperLight Portable X-ray Unit
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: July 7, 2023
Received: July 12, 2023

Dear Mr. Strong:

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)*
K232068

Device Name
HyperLight Portable X-ray Unit

Indications for Use *(Describe)*
The HyperLight Portable X-ray Unit is a diagnostic X-ray system which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and pediatric subjects.

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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510k FDA Consulting

Medical Device Clearances

156 East Granada Blvd. Ormond Beach, FL 32176 386-506-8711

510(k) Summary - K232068

Submitter/Applicant

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Date Prepared: July 10, 2023

Preparer/Consultant

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Device Classification

Trade/Model Names:	HyperLight Portable X-ray Unit
Common Name:	Portable X-ray System
Regulation Name:	Extra-oral 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

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K180561
Applicant:	MobileX Portable X-ray System (Model T-100).
Date Cleared:	April 4, 2018
Regulation Name:	Extra-oral 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

Indications for Use

The device is a diagnostic X-ray system which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and pediatric subjects.

Intended Use

Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.

Device Description

HyperLight Portable X-ray Unit of Changzhou Sifary Medical Technology Co., Ltd., is a handheld x-ray device. The technology of portable x-ray devices was originally developed in the 1950s and was originally designed to be used in situations where there was no access to fixed x-ray units. With new technological possiblities arising, the use of portable handheld devices are becoming more mainstream.

The subject device is designed for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structure by exposing an x-ray image receptor to ionizing radiation. The x-ray source, a tube, is located inside the handheld device. All three conventional types of intraoral receptors can be used with this device—analog x-ray film, digital phosphorous plates, and digital x-ray sensors. The intraoral x-ray detectors are not part of the subject device. The functions of the HyperLight Portable device are supported by software. The software package is of Moderate level of concern and it's not based on the predicate system.

This device is used in general dentistry and is supplied with an internal timer to control the duration of the x-ray source to the patient. The handheld x-ray device is a choice model to assist doctors with special need patients, nursing home patients and patients in the office that cannot be easily moved, as well as other special situations. The choice of an x-ray generator is a matter of functional utility in the dental operatory and personal preference by the medical professional.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Device Characteristic	Subject Device HyperLight Portable X-ray Unit	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
510(k) Owner	Changzhou Sifary Medical Technology Co., Ltd. (China)	Denterprise International, Inc. (USA)	NA
Classification & Product Code	872.1800; EHD	872.1800; EHD	Similar
Intended Use	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Similar
Indication for Use	The device is a diagnostic X-ray system which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and pediatric subjects.	The device is a diagnostic X-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic x-ray images using intra-oral receptors. Its use is intended for both adults and pediatric subjects.	Similar
Size	11.85” x 4.58” x 9.97”	6.5” x 6.0” x 10.5”	**Difference of design, size**
Source to Skin Distance	20 cm	20.5 cm	**Difference .5 cm**
Cone diameter	5.7 cm	6.0 cm	**Difference .3 cm**

Device Characteristic	Subject Device HyperLight Portable X-ray Unit	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
User interface	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, and tooth selection icons on an LCD display.	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display.	**Difference; subject device does not set image-receptor type**
Backscatter radiation protection	159.5mm dia. 13mm thick Pb-filled acrylic plastic scatter shield	153mm dia. 12mm thick Pb-filled acrylic plastic scatter shield	**6.5 mm difference in diameter and 1 mm difference in thickness**
Exposure switch	Exposure trigger at the lower front area of the main body or remote switch.	Exposure button at front cover on right hand side or remote switch.	**Different location**
Electrical Information			
Exposure time	0.02 ~ 2.0 seconds in .01-.40s increments (20 steps)	0.01 ~ 1.3 seconds in 0.01 or 0.05 increments	**Difference; subject device has higher exposure time limits and varying increments**
Time accuracy	±5% or ±20ms, whichever is greater	± (10% +1 ms)	**Slight difference**
mA	2.5mA	2mA	**Subject has greater mA**
kVp	65kVp	70kVp	**Subject has lesser kVp**
Waveform	Constant Potential (DC)	Constant Potential (DC)	Similar
Total Filtration	1.8mmAl	1.5mmAl	**Subject has greater Total Filtration**

Device Characteristic	Subject Device HyperLight Portable X-ray Unit	Predicate Device Mobile-X Portable X-ray System (K180561)	Comparison
Performance standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 62366 ISO 14971 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 IEC 62366 ISO 14971	**Difference; subject device tested to IEC61223-3-4**

The above comparison shows the subject and predicate devices have substantially similar technological characteristics. Differences show up in the shape, size, design of the device and those are in cm and mm measurements of slight difference. The exposure time is slightly less with the subject device matched to the predicate. The differences of the device are minor and do not raise new issues of safety and effectiveness.

Non-Clinical Performance Data

The following performance was completed on the subject device in support of the substantial equivalence determination of the predicate device. Clinical data was not needed to support substantial equivalence.

- Electrical Safety and EMC
- Software Validation
- Biocompatibility
- Usability
- Clinical Comparison
- Risk Assessment

- All tests were performed in accordance with ISO standards and tests are recognized by FDA.
- None of the standards were adapted for application to the device under review.
- There were no requirements of any standard that were not applicable to the device.

- No deviations from the standards were applied.
- No differences exist between the tested device and the device to be marketed.
- Conformity with all standards was determined by the device manufacturer, Changzhou Sifary Medical Technology Co., Ltd
- Electrical tests performed by TÜV Rheinland (Shanghai) Co., Ltd.

Specific Guidance Document

There are three FDA Specific Guidance Documents associated with the device:

- *Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use.* This manufacturer utilized this guidance to develop this device to ensure the safety of this device for both the operators and the patients.
- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. Details of this guidance are provided within the Software Validation Report.
- *Pediatric Information for X-ray Imaging Device Premarket Notifications.* The submission includes pediatric patients in the Indications for Use and labelling.

Labels

The labels on the device show that this device conforms to the following:

21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,
21 CFR 1020.30: Diagnostic x-ray systems and their major components,
21 CFR 1020.31: Radiographic Equipment

Substantial Equivalence

The above comparison chart shows the subject and predicate devices are substantially equivalent in technological characteristics.

Both devices have:

- The same function and used in the same environment.
- The same indications for use and the same intended use.
- The same manufacturing process and technological characteristics.
- Both devices have completed the ISO standardized testing and have passed and the tests are in the comparison chart shown above.

Conclusion

The subject and predicate device have the same indications for use, the same intended use and the same technological characteristics. The **HyperLight Portable X-ray Unit** performs the same identical functions, in the same environment as the predicate device. **HyperLight Portable X-ray Unit** uses the same technology as the predicate device, based on well-known technology. **HyperLight Portable X-ray Unit** is as safe and effective as the predicate device. We believe the subject device does not introduce any new safety concerns and is substantially equivalent to the predicate device. **In conclusion, the subject device, HyperLight Portable X-ray Unit, is at least as safe and effective as the predicate device and warrants a finding of substantial equivalence to the legally marketed device.**