



November 2, 2023

Lumendo AG
Mark Bispinghoff
Coo
Chemin du Closel 5
Renens, VD 1020
Switzerland

Re: K232076
Trade/Device Name: Fibercure
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: QNF
Dated: October 4, 2023
Received: October 4, 2023

Dear Mark Bispinghoff:

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,

The logo of the U.S. Food and Drug Administration (FDA) is displayed in a light blue color. It consists of the letters "FDA" in a stylized, bold font.

Bobak
Shirmohamma
di -S

For Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K232076

Device Name

Fibercure

Indications for Use (Describe)

For light curing polymerization of small areas of dental materials capable of curing in the 385 – 425 nm wavelength range.

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 K232076

Prepared on: 2023-10-31

This 510(k) summary information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1 Applicant

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2 Device

DEVICE NAME: Fibercure
COMMON NAME: Ultraviolet activator for polymerization
CLASSIFICATION NAME: Laser activator for polymerization
REGULATION NUMBER: 872.6070
PRODUCT CODE: QNF

3 Legally marketed predicate devices

DEVICE TYPE	510(k) #	PREDICATE TRADE NAME	PRODUCT CODE
PRIMARY PREDICATE	K220826	LED Curing light DB686 nano	EBZ
REFERENCE	K201904	Ultraviolet activator for polymerization	QNF

4 Device description summary

Fibercure is a handheld dental curing light intended for light curing polymerization of small areas of dental materials capable of curing in the 385 – 425 nm wavelength range. Fibercure functions by delivering light energy to photocurable dental materials, which utilize the light energy to induce a photopolymerization reaction.

Fibercure consists of a pen-shaped handpiece, that is powered with a detachable, rechargeable battery. The handpiece features a user interface containing two push buttons and three status LEDs. The hand-piece is equipped with a solid-state laser diode to generate light energy at a wavelength of $405 \pm 5\text{nm}$ and a power of 40 mW. The laser diode is coupled to single-use cure tips containing an optical fiber of 200 μm diameter. The cure tip emits light with an irradiance of 1800 – 2200 mW/cm^2 and allows the light to be precisely targeted on the area to be photocured. Fibercure has 2 operation modes to provide either 10 or 20 second irradiation. Fibercure is delivered with a charging stand that is connected to the mains power using a USB power supply. It provides two charging stations and a photometer to confirm the intensity of the emitted light.

Fibercure's handpiece is manufactured from anodized aluminum and houses the electronic assembly. The cure tip consists of a silica-ETFE optical fiber, a stainless-steel fiber guide, a plastic housing and a ceramic ferrule. The detachable battery, charging base and power supply are manufactured from injection-molded plastic.

5 Indications for Use

For light curing polymerization of small areas of dental materials capable of curing in the 385 – 425 nm wavelength range.

6 Indications for Use Comparison

The subject device, Fibercure, is indicated for light curing polymerization of small areas of dental materials capable of curing in the 385 - 425 nm wavelength range. The predicate device is indicated for light curing polymerization of dental composites, luting materials, cements and other light cured materials. While the subject device refers to the photocuring of dental materials in general, the predicate lists examples of such materials but also includes “other light cured materials” which encompasses the general, dental materials referenced by the subject device. This difference, along with specification of the compatible wavelength range, does not result in a new intended use because both result in an intended use for photo-curing of dental materials.

7 Substantial Equivalence Comparison

Fibercure and the predicate device have the same type of use, target users, treatment site, mechanism of action, components, power source, electrical safety classification, operational modes, infection control for the handpiece, and user interface. Where there are differences between Fibercure and the predicate device, they do not raise different questions of safety or effectiveness. The performance testing results demonstrate that Fibercure functions as intended.

The characteristics of the subject and predicate devices are tabulated and compared below:

Device	<u>Subject device</u> Fibercure	<u>Predicate device</u> LED Curing light DB686 nano (K220826)	<u>Reference device</u> Monet Curing Laser (K201904)	Comparison
Intended use	Photocuring of dental materials	Photocuring of dental materials	Photocuring of dental materials	Identical
Indications for use	For light curing polymerization of small areas of dental materials capable of curing in the 385 – 425 nm wavelength range	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	The Monet Curing Laser is a source of illumination for curing photo-activated dental restorative materials and adhesives.	Similar: The subject device is intended for photocuring of dental materials in the 385 – 425 nm wavelength range only.
Type of use	Prescription use	Prescription use	Prescription use	Identical
Target users	Dental Professionals	Dental Professionals	Dental Professionals	Identical
Treatment site	Oral cavity	Oral cavity	Oral cavity	Identical
Mechanism of action	Light irradiation of dental material	Light irradiation of dental material	Light irradiation of dental material	Identical
Handling instructions	1. Clean and disinfect all the surfaces of the handpiece before each use. 2. Attach a cure tip to the device. 3. Cover the handpiece with the disposable Protective Sleeve. 4. Power on the device by pressing the power button. 5. Press the Laser button to activate the light. Press once or twice to select curing time. 6. Once the selected curing time has elapsed, the curing program is automatically terminated.	1. Clean and disinfect all the surfaces of the handpiece and the cure tip before each use. 2. Attach the cure tip to the device. 3. Cover the device with the disposable Protective Sleeve. 4. Operate the rotary switch to Cure to power on the device. 5. Press the Start key to activate the light. Press once or twice to select curing time. 6. Once the selected curing time has elapsed, the curing program is automatically terminated.	1. Disinfect the unit before each use. 2. Ensure a charged battery is attached to the unit and a barrier sleeve is applied. 3. Press the switch to “wake up” the unit and go to Standby status. 4. Press the switch to go to enter the “Ready” status 5. Press the switch to activate the laser for 1 second.	Similar: The subject and the predicate and reference all include steps for disinfection, tip attachment, covering with a protective barrier sleeve, and device activation by operating a switch.

Device	<u>Subject device</u> Fibercure	<u>Predicate device</u> LED Curing light DB686 nano (K220826)	<u>Reference device</u> Monet Curing Laser (K201904)	Comparison
Components	Handpiece, charging base with power meter, cure tip, battery, adapter with power cord, protective sleeve, user manual	Handpiece, charging base with power meter, cure tip, battery, adapter with power cord, protective sleeve, user manual	Handpiece, charging base with power meter, battery, adapter with power cord, protective sleeve, user manual	Identical
FDA-Recognized Standards	IEC 80601-2-60:2019 (Rec.# 4-262) IEC 60601-1:2020 (Rec.# 19-49) IEC 60601-1-2:2020 (Rec.# 19-39) IEC 60825-1:2014 ISO 7405:2018 (Rec.# 4-261) ISO 10993-1:2018 (Rec.# 2-258)	IEC 80601-2-60 IEC 60601-1 IEC 60601-1-2 IEC 62471	IEC 60601-1:2012 IEC 60601-1-2:2020 (Rec.# 19-39) IEC 60825-1:2007 (Rec.# 12-273)	Similar: Electrical safety, EMC, laser safety, and biocompatibility of the subject device was tested according to the currently FDA-recognized consensus standards.
Power source	User-replaceable battery	User-replaceable battery	User-replaceable battery	Identical
Charging power supply	Input: 100 – 240 V, 50 – 60 Hz Output: 5 V, 1.2 A	Input: 100 – 240 V, 50 – 60 Hz Output: 5 V, 1.5 A	Input: 100 - 240 V, 50 - 60 Hz Output: 5 V, 2 A	Similar: the subject, predicate, and reference devices have identical input voltage and frequency and identical output voltage. The subject device has a slightly lower output current.
Electrical safety classification (IEC 60601-1)	Class II, Type B Applied Part	Class II, Type B Applied Part	Class II, Type B Applied Part	Identical
Light source & Laser safety class (IEC 60825-1)	Laser diode, class 3R	Light-emitting diode (LED)	Laser diode, class 4	Similar: the internal light sources within the handpiece are different, but the light exits the device via a light guide in all cases.
Irradiance (at 2 mm distance from the tip)	1800 – 2200 mW/cm ²	1600 – 1800 mW/cm ²	2000 – 2400 mW/cm ²	Similar: The irradiance of the subject device is between the predicate and reference device.

Device	<u>Subject device</u> Fibercure	<u>Predicate device</u> LED Curing light DB686 nano (K220826)	<u>Reference device</u> Monet Curing Laser (K201904)	Comparison
Peak wavelength	405 ± 5 nm	405 nm, 460 nm	450 nm	Similar: The peak wavelength of the subject device is the same as one of the peak wavelengths of the predicate device.
Depth of cure	1.4 ± 0.1 mm	1.7 ± 0.1 mm	2.1 ± 0.1 mm	Similar: all devices pass the ISO 4049:2019, clause 5.2.8 requirement of ≥ 1 mm for class 2, opaque restorative materials.
Operational modes	10 seconds, 20 seconds	10 seconds, 20 seconds	1, 2, or 3 s	Identical (subject & predicate device)
Infection control (Handpiece)	Intermediate/ low-level surface disinfection Use of protective barrier sleeve	Intermediate/ low-level surface disinfection Use of protective barrier sleeve	Intermediate/ low-level surface disinfection Use of protective barrier sleeve	Identical
Infection control (Cure Tip)	Single-use	Reusable Intermediate/ low-level disinfection	Reusable Intermediate/ low-level disinfection	Similar: all devices include infection control mechanisms for the Cure Tip. The subject device features a single-use cure tip, whereas the predicate and reference devices feature reusable tips that require intermediate/ low-level disinfection.
Dimensions (cm)	205 X 18 mm	197 x 13.5 mm	215 X 19 mm	Similar: the dimensions of the subject device lie between those of the predicate and the reference device.
User interface	2 Buttons with indicator lights	2 Buttons with indicator lights	1 Button	Identical (subject & predicate device)

8 Non-Clinical Tests Summary

Non-clinical performance testing was conducted according to FDA guidance “Dental Curing Lights – Pre-market Notification [510(k)] Submissions,” issued March 27, 2006, and recognized consensus standard ISO 10650:2018 (FDA recognition #4-252).

Inspection of connections and operating controls was carried out according to ISO 10650:2018, chapter 7.2.1 and 7.2.2. Irradiance, peak wavelength and depth of cure were measured according to the FDA guidance and ISO 4049:2009, chapter 7.10. Irradiance and depth of cure were compared between the subject and the predicate and reference device.

Fibercure meets the requirements of ISO10650:2018 and the FDA guidance “Dental Curing Lights – Pre-market Notification [510(k)] Submissions”. The determined performance parameters are compatible with the requirements for the intended use and are comparable to those of the predicate device.

9 Conclusion

In conclusion, Fibercure meets the requirements of the applicable standard and guidance, performs as specified and is as safe and effective for its intended use as the predicate device. The Fibercure device shares an identical intended use, and similar indications for use with the predicate device. Fibercure and the predicate device also have the same type of use, target users, treatment site, mechanism of action, components, power source, electrical safety classification, operational modes, infection control for the handpiece, and user interface.

Therefore, the Fibercure device is substantially equivalent to the listed predicate device without raising any different questions of safety or effectiveness.