November 19, 2020

HULASER, Inc.
℅ Dongha Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
Korea, Republic Of

Re: K200693
Trade/Device Name: K2 Mobile
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 10, 2020
Received: March 16, 2020

Dear Dongha Lee:

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,

Purva Pandya
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200693

Device Name
K2 MOBILE

Indications for Use *(Describe)*
K2 mobile laser is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures, including Tooth Whitening and the temporary relief of pain. The Specific indications are as follows:

Endodontic procedures:
Pulpotomy, Root canal therapy

Periodontal procedures:
Sulcular debridement

Implant procedures:
Implant recovery

Surgery procedures:
Biopsies, Crown lengthening, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Gingivectomy, Gingivoplasty, Incision and drainage of abscess, Operculectomy, Papillectomies, Reduction of gingival hypertrophy, Vestibuloplasty

Other procedures:
Gingival troughing, Hemostasis and coagulation, Leukoplakia,
Treatment of aphthous-ulcer canker sores and herpetic,
Laser Assisted whitening,
Topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain and stiffness minor arthritis pain, or muscle spasm, minor sprains and minor muscular back pain; the temporary increase in local blood circulation; the temporary relation of muscle

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 (K200693)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 28, 2020

1. Applicant / Submission Sponsor

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2. Submission Correspondent

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3. Device Identification

Trade/Proprietary Name: K2 MOBILE
Common Name: Dental Diode Laser
Classification Regulation: 21CFR 878.4810
Product Code: GEX,
Device Class: 2

4. Predicate Devices

	Predicate Device 1	Predicate Device 2
Manufacturer	Zolar Technology Inc	Biolase Technology, Inc.
Device Name	Photon Plus	iLaseTM
510(k) number	K162114	K093852

5. Description

The dental diode laser (Model: K2 MOBILE) is a surgical device designed for a wide variety of dental soft tissue procedures. Diode laser is used as a source of invisible infrared radiation for this device and delivered to the treatment area through optical fiber. The optical fiber is

incorporated into a tip. The dental diode laser (Model: K2 MOBILE) is handpiece type using an internal rechargeable battery. The rechargeable battery and battery charger are provided.

6. Indication for use

K2 mobile laser is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures, including Tooth Whitening and the temporary relief of pain. The Specific indications are as follows:

Endodontic procedures:

Pulpotomy, Root canal therapy

Periodontal procedures:

Sulcular debridement

Implant procedures:

Implant recovery

Surgery procedures:

Biopsies, Crown lengthening, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Gingivectomy, Gingivoplasty, Incision and drainage of abscess, Operculectomy, Papillectomies, Reduction of gingival hypertrophy, Vestibuloplasty

Other procedures:

Gingival troughing, Hemostasis and coagulation, Leukoplakia,

Treatment of aphthous-ulcer canker sores and herpetic,

Laser Assisted whitening,

Topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain and stiffness minor arthritis pain, or muscle spasm, minor sprains and minor muscular back pain; the temporary increase in local blood circulation; the temporary relation of muscle

7. Substantial Equivalence

Dental Diode Laser (Model: K2 MOBILE) is substantially equivalent to the predicate devices, Photon Plus (K162114, Zolar Technology Inc) and iLaseTM (K093852, Biolase Technology, Inc.) The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device	Predicate Device 1 (PD1)	Predicate Device 2 (PD2)	Comparison
Manufacturer	HULASER, Inc.	Zolar Technology Inc	Biolase Technology, Inc.	-
Device Name	K2 MOBILE	Photon Plus	iLase™	-
510(k) number	K200693	K162114	K093852	-
Product Code	GEX	GEX	GEX	Same
Regulatory Class	2	2	2	Same
Indications for Use	K2 mobile laser is intended for use by dentists for excision, incision, vaporization, ablation and coagulation of oral soft tissue procedures, including Tooth Whitening and the temporary relief of pain. The Specific indications are as follows: **Endodontic procedures:** Pulpotomy, Root canal therapy **Periodontal procedures:** Sulcular debridement **Implant procedures:** Implant recovery **Surgery procedures:** Biopsies, Crown lengthening, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Gingivectomy, Gingivoplasty, Incision and drainage of abscess, Operculectomy,	**Dental Soft Tissue Indications** Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Exposure of Unerupted teeth Fibroma removal Frenectomy Gingival Troughing for crown impressions Gingivectomy Gingivoplasty Hemostasis and coagulation Gingival incision and excision hemostasis Implant recovery Incision and drainage of abscess Leukoplakia Operculectomy Oral papillectomies Pulpotomy as an adjunct to root canal therapy Reduction of gingival hypertrophy Soft tissue crown lengthening Gingival bleeding index Excisional and incisional biopsies	The iLase™ dental soft tissue laser is a surgical device designed for a wide variety of dental soft tissue procedures and laser periodontal procedures. **Dental Soft Tissue Indications:** Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth Fibroma removal Frenectomy Frenotomy Gingival troughing for crown impressions Gingivectomy Gingivoplasty Gingival incision and excision Hemostasis and coagulation Implant recovery Incision and drainage of abscess Leukoplakcia Operculectomy	Equivalent (Included in the indications of PD1)

	Papillectomies, Reduction of gingival hypertrophy, Vestibuloplasty **Others procedures:** Gingival troughing Hemostasis and coagulation Leukoplakia Treatment of aphthous-ulcer canker sores and herpetic Laser Assisted whitening Topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain and stiffness minor arthritis pain, or muscle spasm, minor sprains and minor muscular back pain; the temporary increase in local blood circulation; the temporary relation of muscle	Treatment of aphthous ulcer canker sores and herpetic. Vestibuloplasty. **Laser Periodontal Indications** Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including: probe depth, attachment loss and tooth mobility) Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium. **Tooth Whitening Indications** Laser Assisted whitening/bleaching of teeth. Light activation for bleaching materials for teeth whitening. **Pain Indications** Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness minor arthritis pain, or muscle spasm, minor sprains and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	Oral papillectomies Pulpotomy Pulpotomy as an adjunct to root canal therapy Reduction of gingival hypertrophy Soft tissue crown lengthening Treatment of canker sores, herpetic and aphthous ulcers of the oral rnucosa. Vestibuloplasty Tissue retraction for impression **Laser Periodontal Procedures, including:** Laser soft tissue curettage Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility).	
Principle of operation	Laser diode is used as a source of invisible infrared radiation for this device and delivered to the treatment area through optical fiber.	Laser diode is used as a source of invisible infrared radiation for this device and delivered to the treatment area through optical fiber.	Laser diode is used as a source of invisible infrared radiation for this device and delivered to the treatment area through optical fiber.	Same

Laser Medium	Diode Laser	Diode Laser	Diode Laser	Same
Laser Classification	Class IV (4) Laser	Class IV (4) Laser	Class IV (4) Laser	Same
Laser Wavelength	980nm	980nm	940nm	Same as the PD1
Laser Power range	0~6W	0~10W	0~5W	Equivalent (Included in the rage of PD1) Similar (Refer to Note 1.)
Operation mode	Continuous (CW) mode, Pulse mode	Continuous (CW) mode, Pulse mode	Continuous (CW) mode, Pulse mode	Same
Pulse width/interval	On/off time: 50ms (Pulse mode 1) On/off time: 5ms (Pulse mode 2)	0.1ms to 9.9s	Unknown	Equivalent (Included in the rage of PD1) (Refer to Note 1.).
Pulse repetition rate	10Hz (Pulse mode 1) 100Hz (Pulse mode 2)	1Hz to 5,000Hz	Unknown	Different (Refer to Note 1.).
Aiming Beam	635nm, 5 mW	650nm, 2mW	635nm, 5 mW	Same as the PD2
Fiber core diameter	400 μm	400 μm	400 μm	Same
Power Input	Rechargeable Lithium Ion battery: 3.7V, 1700 mA (Battery charger: AC 100-240V, 47-63Hz)	Rechargeable lithium polymer battery: 7.4V, 5A (Battery charger: AC 100-240V, 50/60Hz)	Rechargeable Lithium Ion battery: 3.6V, 650 mA (Battery charger: AC 90-230V, 50-60Hz)	Different (Refer to Note 2.).
Prescription or OTC	Prescription	Prescription	Prescription	Same
Intended User	Licensed practitioner	Licensed practitioner	Licensed practitioner	Same

Note 1.

: Laser output power range of the subject device is 0 to 6.0W. (The maximum output power is 3.5W on CW mode and the maximum peak power is 6.0W on pulsed mode.) The range is within the range (0 to 10W) of the predicate device 1 (K162114) and similar to the predicate device 2 (K093852, 0 to 5W).

Pulse width/interval and pulse repetition rate of the subject device are that on/off time is 50ms (10Hz) on pulse mode 1 and on/off time is 5ms (100Hz) on pulse mode 2. The predicate device 1 (K162114) has a specification of the pulse width/interval and pulse repetition rate (0.1ms to 9.9s 1Hz to 5,000Hz). The specifications of the predicate device 2 (K093852) is unknown.

The laser safety and performance test was conducted according to IEC 60825-1. The device safety and performance test was conducted according to IEC 60601-1, IEC 60601-2-22, 21CFR1040.10 and 21CFR1040.11 with the above differences. The testing results show that these differences do not raise different questions of safety and effectiveness.

(The safety and performance test reports are attached in this submission).

Note 2.

: The subject device uses an internal rechargeable lithium-ion battery (DC 3.7V,1700mA). The predicate device 1 (K162114) uses an internal rechargeable lithium-polymer battery (DC 7.4V, 5A), and the predicate device 2 (K093852) uses an internal rechargeable lithium-ion battery (DC 3.6V, 650mA).

The internal battery safety and performance test was conducted according to IEC 62133. The device safety and performance test was conducted according to IEC 60601-1 and IEC 60601-2-22. The testing results show that these differences do not raise different questions of safety and effectiveness.

(The safety and performance test reports are attached in this submission).

8. Reprocessing

We tested and validated the reprocessing process according to FDA reprocessing guidance, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.”. The results show that the designed reprocessing processes are effective to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.

9. Biocompatibility

The biocompatibility tests of patient contact part (Tip, optical fiber is incorporated into tip, External communicating device - Blood path, indirect / limited contact duration: <24 hours) were performed in accordance with the following FDA recognized standards

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

10. Electrical Safety and Electromagnetic compatibility

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following FDA recognized standards.

- IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-22:2007+A1:2012, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency.
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements
- 21 CFR 1040.10 and 1040.11
- IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests

11. Performance Testing - Nonclinical

1) Laser performance - Classification, Accessible emission level

The test was performed in in accordance with the FDA recognized standard, IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements, Clause 9, and 21CFR1040.10.

2) Laser output power testing – Protection against unwanted and excessive output, Accuracy of control

The test was performed in accordance with the FDA recognized standard, IEC 60601-2-22:2007+A1:2012, Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, Clause 201.10 and 201.12, and 21CFR1040.11

12. Conclusion

In comparing between the subject device and the predicate device, there are the same product code, regulatory classification, indications for use, principle of operation, laser classification, laser medium, laser operation mode, using a rechargeable battery, prescription use and intended user. Although there are some differences (laser output specifications and internal battery specifications), the safety and performance test reports are supported to the safety and effectiveness of the subject device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate devices.