February 26, 2021

DentLight Inc.
Richard Liu
President
1825 Summit Ave. Ste 210
Plano, Texas 75074

Re: K201387
Trade/Device Name: Ultrafast, Ultrafast Plus, Ultrafast Lite
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: NVK, GEX
Dated: February 9, 2021
Received: February 12, 2021

Dear Richard Liu:

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,

For Michael Adjodha
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201387

Device Name
Ultrafast/Ultrafast Plus/Ultrafast Lite

Indications for Use *(Describe)*
Dental soft tissue indications: incision, excision, vaporization, ablation, and coagulation of oral soft tissues including the following:
• Gingival troughing for crown impression
• Gingivectomy
• Gingivoplasty
• Gingival incision and excision
• Hemostasis and coagulation
• Excisional and incisional biopsies
• Exposure of unerupted teeth
• Fibroma removal
• Frenectomy and frenotomy
• Implant recovery
• Incision and drainage of abscess
• Leukoplakia
• Operculectomy
• 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 ulcers
• Vestibuloplasty
• Tissue retraction for impression

Laser periodontal indications including:
• Sulcular debridernent (curettage, 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).
• Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket.

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.

IV. 510(k) Summary K201387

This summary of 510(k) substantial equivalence is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

1. APPLICANT

DentLight Inc.
1825 Summit Ave., Suite 210
Plano, TX 75074

Phone: 972-889-8857
Fax: 972-346-6550
Contact Person: Richard Liu

Date Prepared: Feb. 8, 2021

2. DEVICE NAME

Proprietary Name: Ultrafast/Ultrafast Plus/Ultrafast Lite

Common/Usual Name: Dental Diode Laser

Classification Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology (878.4810)

Product Code: GEX

3. PRIMARY PREDICATE DEVICE

Styla Microlaser (K081214), manufactured by Zap Lasers, LLC.

REFERENCE DEVICE

K2 Mobile (K200693), manufactured by Hu Laser.

4. INTENDED USE / INDICATIONS FOR USE

Dental soft tissue indications: incision, excision, vaporization, ablation, and coagulation of oral soft tissues including the following:

- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia

- Operculectomy
- 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 ulcers
- Vestibuloplasty
- Tissue retraction for impression

Laser periodontal indications including:

- Sulcular debridement (curettage, 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).
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket.

5. DEVICE DESCRIPTION

The Ultrafast series (Ultrafast, Ultrafast Plus, and Ultrafast Lite) are cordless diode laser systems designed for a wide variety of dental soft tissue procedures. The products have three separate models under the model names: Ultrafast, Ultrafast Plus and Ultrafast Lite. They use solid-state laser diodes as sources of infrared radiation. The energy from the infrared radiation is delivered to the treatment site via a single-use fiber optic tip.

The product kit consists of a laser handpiece, laser goggles, charging stand, power adapter, laser shield, barrier sleeves, product warning labels and instructions for use. The laser handpiece is constructed from anodized aluminum and contains a single-use, disposable fiber optic tip and main body containing laser diode, main control and a rechargeable battery assembly. The main control houses the control circuitry with microprocessor and user interface to control and deliver the laser and a green aiming beam to guide the laser procedures. The charging stand allows for the placement of the handpiece in a holder with electrical connection to the power adapter as the source for charging the rechargeable battery.

Based on the wavelength and power of the laser diodes used, the kit can be preconfigured into three separate models:

Trade Name	**Wavelength (nm)**	**Max CW Power (Watt)**
Ultrafast	808	3
Ultrafast Plus	980	3
Ultrafast Lite	808	1.5

6. DEVICE CHARACTERISTICS AND SUBSTANDTIAL EQUIVALENCE

Ultrafast/Ultrafast Plus/Ultrafast Lite are substantially equivalent to the primary predicate device Styla Microlaser (K081214), manufactured by Zap Lasers, LLC (now Denmat) and the reference device K2 Mobile (K200693), manufactured by Hu Laser. A comparison table on performance and technology with the predicate and reference devices lists key features and characteristics of the subject and predicate devices. It shows the subject products have the same technology characteristics as the predicate devices.

Subject Device Performance and Technological Comparison

Parameter\ Name		Ultrafast / Ultrafast Plus /Ultrafast Lite	Styla Microlaser (Primary Predicate Device)	K2 MOBILE (Reference Device)
Manufacturer		DentLight	Zap Laser/Denmat	Hu Laser
510(k) Number		K201387	K081214	K200693
Light Source		Diode Laser	Diode Laser	Diode Laser
Regulation Number		878.4810	878.4810	878.4810
Device Class		II	II	II
Product Code		GEX	GEX	GEX
Peak Wavelength Range (nm)		808±10 nm (Ultrafast/Ultrafast Lite) 980±10 nm (Ultrafast Plus)	808±5 nm	980±10 nm
Maximum CW Power (Watt)		3 (Ultrafast/Ultrafast Plus) 1.5 (Ultrafast Lite)	1.5	3.5
Maximum Pulse Power (Watt)		5 (Ultrafast/Ultrafast Plus) 2 (Ultrafast Lite)	2	6
Power Accuracy (W)		±20%	±20%	±20%
Fiber Core Diameter (µm)		400	400	400
Aiming Beam		525 (±10nm, 0.6mW)	650 (±10nm, 0.5mW)	635 (5 mW)
OPERATION MODE		Continuous / Pulse	Continuous / Pulse	Continuous / Pulse
Display		LCD	OLED	OLED
Audible Notification		Yes	Yes	Yes
Visual Notification		Yes	Yes	Yes
Length (without fiber tip)		163	175	205
Weight (grams)	Handpiece	100	55	135
	Charging Stand	88	340	150
Battery		Lithium ion	Lithium ion	Lithium ion
Power Supply Input		100-240V, 50/60Hz	Input: 100-240V, 50-60Hz	Input: 100-240V, 50-60Hz
Structure		Ergonomic aluminum wand	Ergonomic aluminum wand	Ergonomic aluminum/plastic wand
Compliance Standards		IEC 60601-1; IEC 60601-1-2; IEC 60825-1; IEC 60601-2-22	IEC 60601-1; IEC 60825-1; IEC 60601-2-22	IEC 60601-1; IEC 60825-1; IEC 60601-2-22

Subject Device Indications for Use Comparisons

Parameter\ Name	Ultrafast / Ultrafast Plus /Ultrafast Lite	Styla Microlaser (Primary Predicate Device)	K2 MOBILE (Reference Device)
Manufacturer	DentLight	Zap Laser/Denmat	Hu Laser
510(k) Number	K201387	K081214	K200693
Indications for Use	Dental soft tissue indications: incision, excision, vaporization, ablation, and coagulation of oral soft tissues including the following: • Gingival troughing for crown impression • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis and coagulation • Excisional and incisional	Intended for ablating, incising, excising, vaporizing, and coagulation of oral soft tissues using a contact fiber optic delivery system. The following are the oralpharngeal indications for use for which the device will be marketed: • Excisional and incisional biopsies • Hemostasis assistance	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: • Biopsies • Crown lengthening • Exposure of unerupted teeth • Fibroma removal

	biopsies • Exposure of unerupted teeth • Fibroma removal • Frenectomy and frenotomy • Implant recovery • Incision and drainage of abscess • Leukoplakia • Operculectomy • 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 • Vestibuloplasty • Tissue retraction for impression Laser periodontal indications including: • Sulcular debridement (curettage, 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). • Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket.	• Treatment of aphthous ulcers • Frenectomy and frenotomy • Gingival Incision and Excision • Gingivectomy • Gingivoplasty • Incision and drainage of abscess • Operculectomy • Oral papillectomy • Removal of fibromas • Soft tissue crown lengthening • Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) • Vestibuloplasty	• Frenectomy • Gingival troughing • Gingivectomy • Gingivoplasty • Pulpotomy • Root canal therapy • Hemostasis and coagulation • Leukoplakia • Implant recovery • Incision and drainage of abscess • Operculectomy • Papillectomies • Reduction of gingival hypertrophy • Treatment of Aphthous-ulcer canker sores and herpetic •Vestibuloplasty Periodontal procedures: • Sulcular debridement • 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 • Laser Assisted whitening

Similarities between Ultrafast/Ultrafast Plus/Ultrafast Lite and Predicate/Reference Devices:

- Ultrafast/Ultrafast Plus/Ultrafast Lite have the same indications for use as the predicate/reference devices.
- Ultrafast/Ultrafast Plus/Ultrafast Lite have substantially equivalent operating modes as the predicate/reference devices.
- Ultrafast/Ultrafast Plus/Ultrafast Lite have substantially equivalent design, construction materials, weight, size, performance characteristics and key features as the predicate/reference devices.
- Ultrafast/Ultrafast Plus/Ultrafast Lite are substantially equivalent to the predicate/reference devices in standards compliance.

Differences between the Ultrafast/Ultrafast Plus/Ultrafast Lite and Predicate/Reference Devices:
Ultrafast/Ultrafast Plus/Ultrafast Lite have an LCD display instead of an OLED display by the predicate and reference devices. They use green aiming beams instead of red aiming beams by the predicate and reference devices. The difference in display and aiming beam improves the operator's ease of use and does not raise any substantial equivalence concerns as it has similar performance of the predicate and reference devices. The device modifications do not potentially alter the fundamental scientific technology of the device.

7. NON-CLINICAL PERFORMANCE TESTING

The subject devices have been tested for optical, thermal, electrical and mechanical safety and comply with the electrical and optical safety requirements as the predicate devices: IEC 60601-1, IEC 60601-1-2, IEC 60825-1 and IEC 60601-2-22.

The subject devices have been tested for biocompatibility and comply with ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process.
The subject devices have tested and verified to meet all design specifications that are substantially equivalent to the predicate devices.

8. CONCLUSION

Based on similarities in indications for use and technology together with results from performance testing, we believe that Ultrafast/Ultrafast Plus/Ultrafast Lite Diode Lasers are substantially equivalent to the predicate devices.