DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 25, 2017

LightMed Dental Technology Corp.
Ms. April Cheng
Regulatory Affairs Engineer
5F., No. 96, Luke 5th Rd., Luzhu Dist.
Kaohsiung, Taiwan (R.O.C.) 821
Taiwan

Re: K170073
Trade/Device Name: LightMed Dental Laser System
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: June 23, 2017
Received: June 26, 2017

Dear Ms. Cheng

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

Device Name
Lightmed Dental Laser System

Indications for Use *(Describe)*
The LightMed Dental Laser System is intended for use in intraoral general dental surgery procedures, and in maxillofacial and cosmetic dentistry. It is intended for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue and a variety of hard tissues (tooth and bone).

The LightMed Dental Laser System is indicated for the following oral and maxillofacial surgery and dentistry:
• Hard Tissue Indications of Erbium Laser Energy:
* Caries removal
* Cavity preparation
* Enamel etching
* Excavation of pits and fissures for placement of sealant
• Bone Indications of Erbium Laser Energy:
* Shaving, contouring, and resection of oral osseous tissue (bone)
* Apicoectomy - amputation of the root end
* Cutting bone to prepare a window access to the apex (apices) of the root(s)
* Osteotomy
* Osseous crown lengthening
• Soft Tissue and Periodontal Indications of Erbium Laser Energy:
* Excisional and incisional biopsies
* Exposure of unerupted teeth
* Incision and drainage of abscesses
* Gingival incision and excision
* Gingivoplasties
* Gingivectomies
* Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias
* Implant recovery
* Frenectomies and frenotomies
* Fibromatosis (fibroma removal)
* Benign and malignant lesion removal
* Operculectomy
* Oral papillectomies
* Reduction of gingival hypertrophy
* Soft tissue crown lengthening
* Preprosthetic surgery: flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papillomas, fibromatoses benign growths, vestibuloplasty
* Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
• Endodontal Indications of Erbium Laser Energy:
* Tooth preparation to obtain access to root canal
* Pulpotomy
* Pulpotomy as an adjunct to root canal therapy
* Pulp extirpation
* Root canal debridement and cleaning

* Root canal preparation including enlargement

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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Section 5 510(k) Summary

I. SUBMITTER

LightMed Dental Technology Corp.
5F., No. 96, Luke 5th Rd., Luzhu Dist., Kaohsiung City, Taiwan, R.O.C.
TEL: +886 7 695 5111
FAX: +886 7 695 5211
Contact Person: April Cheng / Regulatory Affairs Engineer
Date Prepared: Jun 03, 2017

II. DEVICE

Trade name: LightMed Dental Laser System
Model name: Sapphire
Classification name: Laser Instrument, Surgical, Powered
Classification Panel: General & Plastic Surgery
Regulation number: 21 CFR 878.4810, Class II
Product code: GEX

III. PREDICATE DEVICE

Substantial equivalence to the following predicate device is as follows:

LITETOUCH Dental Laser System	K061966	Decision Date:9/27/2006

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

LightMed Dental Laser System is an erbium: yttrium aluminium garnet (Er:YAG) solid-state laser that provides optical energy at 2940 nm. LightMed Dental Laser System is a delicate integrate device of optical, mechanic, electronic, water and gas, which is consists of a control panel, system controller, laser applicator, power supplies and discharger, laser cooling module, spray water module, footswitch and external remote interlock connector. The laser console is embedded in the laser handpiece, delivers laser energy to the treatment site through a laser tip attached to a handpiece. The laser

is activated by means of a footswitch. Various laser tips are available for different clinical applications. The LightMed Dental Laser System is intended for use in intraoral general dental surgery procedures, and in maxillofacial and cosmetic dentistry. It is intended for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue and a variety of hard tissues (tooth and bone).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Trade name	LightMed Dental Laser System	LITETOUCH Dental Laser System
Model name	Sapphire	LITETOUCH™
510(k) number	K170073	K061966
Unit	11.8 x 17.3 x 35.8 in (30 x 44 x 91 cm)	10.25 x 15.75 x 15.75 in (26 x 40 x 40 cm)
Weight	77 lbs (35 kg)	44 lbs (20 kg)
Operating Voltage	100-230 VAC	100-230 VAC
Electrical Frequency	50 / 60 Hz	50 / 60 Hz
Electrical Requirement	Single Phase	Single Phase
Current Rating	12 A	13 A
Optical Frequency	Up to 50 Hz	Up to 50 Hz
Spot Size	0.2-1.0 mm (Tip dependent)	0.2-1.0 mm (Tip dependent)
Tip category	1. 1.3×19 mm 2. 1.3×14 mm 3. 1.0×17 mm 4. 0.8×14 mm 5. 0.6×17 mm 6. Side Firing 1.3×19 mm 7. Chisel	1. 1.3 x 19 mm 2. 1.3 x 17 mm 3. 1.3 x 14 mm 4. 1.0 x 17 mm 5. 1.0 x 14 mm 6. 0.8 x 17 mm 7. 0.8 x 14 mm 8. 0.6 x 17 mm 9. 0.4 x 17 mm 10. Implants tips, 1.3 x 19 mm 11. Chisel tip

Laser Tip Material	sapphire	sapphire
Handpiece Material	Aluminum alloy	Aluminum alloy
Type of protection against electrical shock	Class I ME Equipment	Class I ME Equipment
Degree of protection against electrical shock	Type BF Equipment	Type BF Equipment
Laser Classification	4	4
Laser Energy Source	Er: YAG (Erbium: Yttrium-Aluminium-Garnet)	Er: YAG (Erbium: Yttrium-Aluminium-Garnet)
Wavelength	2.94 μm (2940 nm)	2.94 μm (2940 nm)
Pumping Source	Flashlamp	Flashlamp
Delivery Component	Applicator with reflector and optics	Applicator with reflector and optics
Pulsing System	Pulse	Pulse
Pulse Rate	Up to 50Hz	Up to 50Hz
Average Power	0.5-8.4 W	0.5-8.4 W
Maximum Pulse Energy	700 mJ	700 mJ
Pulse Duration	< 800 μs	< 800 μs
Device System	Sapphire is an advanced microprocessor-controlled laser system, composed of the following sub-systems: • Control Panel • System Controller • Laser Applicator • Water Spray Module	LiteTouch is an advanced microprocessor-controlled laser system, composed of the following sub-systems: • Control Panel • System Controller • Laser Applicator

	• Power Supply and Discharger • Laser Cooling Module • Footswitch • Remote Interlock Connector	• Water Spray Module • Power Supply and Discharger • Laser Cooling Module • Footswitch • Remote Interlock Connector
Intended Use	**Hard Tissue Indications of Erbium Laser Energy:** * Caries removal * Cavity preparation * Enamel etching * Excavation of pits and fissures for placement of sealant **Bone Indications of Erbium Laser Energy:** * Shaving, contouring, and resection of oral osseous tissue (bone) * Apicoectomy - amputation of the root end * Cutting bone to prepare a window access to the apex (apices) of the root(s) * Osteotomy * Osseous crown lengthening **Soft Tissue and Periodontal Indications of Erbium Laser Energy:** * Excisional and incisional biopsies * Exposure of unerupted teeth * Incision and drainage of abscesses	**Hard Tissue Indications of Erbium Laser Energy:** * Caries removal * Cavity preparation * Enamel etching * Enameloplasty * Excavation of pits and fissures for placement of sealant **Bone Indications of Erbium Laser Energy:** * Contact and non-contact cutting * Shaving, contouring, and resection of oral osseous tissue (bone) * Apicoectomy - amputation of the root end * Cutting bone to prepare a window access to the apex (apices) of the root(s) * Osteoplasty * Osteotomy * Osseous crown lengthening **Soft Tissue and Periodontal Indications of Erbium Laser Energy:** * Excisional and incisional biopsies * Exposure of unerupted teeth * Incision and drainage of abscesses

	* Gingival incision and excision * Gingivoplasties * Gingivectomies * Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias * Implant recovery • Frenectomies and frenotomies * Fibromatosis (fibroma removal) * Benign and malignant lesion removal * Operculectomy * Oral papillectomies * Reduction of gingival hypertrophy * Soft tissue crown lengthening * Preprosthetic surgery: flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papillomas, fibromatoses benign growths, vestibuloplasty * Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)	* Gingival incision and excision * Gingivoplasties * Gingivectomies * Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias * Gingival troughing for crown impressions * Hemostasis * Implant recovery • Frenectomies and frenotomies * Fibromatosis (fibroma removal) * Benign and malignant lesion removal * Operculectomy * Oral papillectomies * Reduction of gingival hypertrophy * Soft tissue crown lengthening * Preprosthetic surgery: flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papillomas, fibromatoses benign growths, vestibuloplasty * Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

	Endodontal Indications of Erbium Laser Energy: * Tooth preparation to obtain access to root canal * Pulpotomy * Pulpotomy as an adjunct to root canal therapy * Pulp extirpation * Root canal debridement and cleaning * Root canal preparation including enlargement	**Endodontal Indications of Erbium Laser Energy:** * Tooth preparation to obtain access to root canal * Pulpotomy * Pulpotomy as an adjunct to root canal therapy * Pulp extirpation * Root canal debridement and cleaning * Root canal preparation including enlargement

VI. PERFORMANCE DATA

The LightMed Dental Laser System complies with the following applicable federal and international safety and performance standards:

* US Federal Performance Standards 21 CFR 1040.10 and 1040.11 for Class IV laser products
* IEC 60825-1:2014
* AAMI/ANSI 60601-1: 2005/(R)2012
* IEC 60601-2-22:2007+A1:2012
* IEC 60601-1-2:2014
* IEC 60601-1-6:2013
* IEC 62366-1:2015
* IEC 62304:2006
* ISO 10993-1:2009
* ISO 10993-5:2009
* ISO 10993-10:2010
* ISO 10993-11:2006
* USP 151:2016
* AAMI / ANSI ST79:2013

* AAMI TIR-30:2011

* AAMI TIR-12:2004

VII. CONCLUSIONS

The LightMed dental Laser System is substantially equivalent to the predicate device in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The LightMed Dental Laser System is designed to comply with applicable federal and international safety and performance standards. There are no new safety and effectiveness issues being raised.