July 11, 2018

Lazon Medical Laser Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K180967
Trade/Device Name: Dental Diode Laser System, Models: Solace-808 and Solace-976
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: April 3, 2018
Received: April 13, 2018

Dear Diana Hong:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180967

Device Name
Dental Diode Laser System
Models: SOLASE-808 and SOLASE-976

Indications for Use *(Describe)*
The indications for use of the subject device are given below.
1. 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:
- fiborma removal
- frenectomy
- frenotomy
- gingival troughing for crown impressions
- gingivectomy
- gingivoplasty
- hemostasis and coagulation
- implant recovery
- incision and drainage of abscess
- operculectomy
- pulpotomy
- soft tissue crown lengthening
- treatment of herpetic and aphthous ulcers of the oral mucosa.

2. Laser periodontal procedures
- 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.)

3. Whitening
- light activation for bleaching materials for teeth whitening
- laser-assisted whitening/bleach of teeth

4. Pain Relief
- 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 strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K180967

1. Date of Preparation: 7/10/2018

2. Sponsor Identification

Lazon Medical Laser Co., Ltd.
No.123, Hezuo Street, Dadong District, Shenyang, 110179, Liaoning, China.

Establishment Registration Number: Not yet registered

Contact Person: Gen Cheng
Position: General Manager
Tel: +86-24-88327588
Email: gen,cheng@lazonlaser.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Device Name: Dental Diode Laser System
Model: SOLASE-808 and SOLASE-976
Common Name: Diode Laser

Regulatory Information

Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Review Panel: General and Plastic Surgery

Indications for Use:
The indications for use of the subject device are given below.
1. 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:
- fiborma removal
- frenectomy
- frenotomy
- gingival troughing for crown impressions
- gingivectomy
- gingivoplasty
- hemostasis and coagulation
- implant recovery
- incision and drainage of abscess
- operculectomy
- pulpotomy
- soft tissue crown lengthening
- treatment of herpetic and aphthous ulcers of the oral mucosa.

2. Laser periodontal procedures
- 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.)

3. Whitening
- light activation for bleaching materials for teeth whitening
- laser-assisted whitening/bleach of teeth

4. Pain Relief
- 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 strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

Device Description

The SOLASE dental diode laser is a surgical and therapeutic device produced by Lazon Medical Laser Co., Ltd., designed for dental soft tissue indications, laser periodontal procedures, as well as teeth whitening and pain relief. It cannot be used for oral hard tissue.

The SOLASE laser uses a laser diode as the beam source to radiate invisible infrared light, which is delivered to the operating area by optical fiber. It can generate a short laser pulse up to 10μs of interval. The SOLASE laser provides two different models with two different wavelengths - 808nm and 976nm, to meet customers' various requirements.

The SOLASE laser is a Class 4 laser product which may cause injuries in improper handling. Therefore, it MUST be operated only by trained and qualified personnel.

5. Identification of Predicate Device and Reference Device

Predicate Device
510(k) Number: K121286
Product Name: Epic 10 Diode Laser System
Model: Epic 10
Manufacturer: Biolase Technology, Inc.

Reference Device
510(k) Number: K103667
Product Name: Sapphire ST Portable Laser
Manufacturer: Denmat Holdings LLC.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI ES 60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- 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
- IEC 60601-2-22:2012, Medical Electrical Equipment – Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment.
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.
- 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
- Performance data showing that the difference between the set average peak power and the measured average peak power meets performance criterion for the range of laser pulse specifications.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device K121286	Reference Device K103667
Product Code	GEX	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	II	II	II
Indications for Use	1. 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: - fiborma removal - frenectomy - frenotomy - gingival troughing for crown impressions - gingivectomy - gingivoplasty - hemostasis and coagulation - implant recovery - incision and drainage of abscess - operculectomy - pulpotomy-soft tissue crown lengthening-treatment of herpetic and aphthous ulcers of	1. 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	The Sapphire ST Portable Diode Laser is intended for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fiber optic delivery system. Indications include excision and incision biopsies;, hemostatic assistance; treatment of apthous ulcers; frenectomv; frenotomny; gingival incision and excision; gingivectomny; gingivoplasty; incising and draining abscesses; operculectony; oral papillectomy; removal of fibromias; Soft tissue crown lengthening; sulcular debridement (removal of diseased or inflamied soft tissue in the periodontal pocket); tissue retraction

	the oral mucosa.	abscess * Leukoplakia * Operculectomy * Oral papillectomnies * 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 mucosa. * Vestibuloplasty * Tissue retraction for impression	forimpression; vestibuloplasty, and light activation of bleaching materials for teeth whitening, laser-assisted bleaching /whitening of teeth.
	2. Laser periodontal procedures - 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.)	2. Laser Periodontal Procedures * 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.)	

	3. Whitening - Light activation for bleaching materials for teeth whitening * Laser-assisted whitening/bleaching of teeth	3. Whitening * Light activation for bleaching materials for teeth whitening * Laser-assisted whitening/bleaching of teeth	
	4. Pain Relief - 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 strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	4. Pain Relief * 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 strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	
Model	SOLASE-808 and SOLASE-976	Epic 10	/
Laser Classification	N(4)	N(4)	N(4)
Dimensions	13.8cm×14.2cm×16.8cm	14.5cm×11.2cm×16.5cm	Unknown
Weight	1.3kg	1.1kg	1.2kg
Power Supply	100-240VAC	100-230VAC	100-240 VAC
Current Frequency	50-60Hz	50-60Hz	50-60Hz
Laser Medium	AlGaAs	InGaAsP	Unknown
Wavelength	SOLASE-808: 808nm SOLASE-976: 976nm	940±10nm	808±5nm
Max Output	CW mode:	10W	CW: 3W

	7W@SOLASE-808, 10W@SOLASE-976 Pulse mode: 12W@SOLASE-808, 16W@SOLASE-976		Pulse mode: 5W
Max Peak Pulse Power	SOLASE-808: 12W SOLASE-976: 16W	10W	5W
Max Average Pulse Power	SOLASE-808: 6.3W (When peak power is 0.1~7W) and 6W (When peak power is 7.1~12W); SOLASE-976: 9W (When peak power is 0.1~10W) and 8W (When peak power is 10.1~16W)	Unknown	2.5W
Max Power Density	SOLASE-808: 222.8W/mm^2 SOLASE-976: 318.3W/mm^2	318.3W/mm^2	23.9 W/mm^2
Power Modes	Continuous and Pulse	Continuous and Pulse	Continuous and Pulse
Pulse Length	2.7m	Unknown	Unknown
Pulse Duration	0.01ms-0.9s	0.01ms-20ms	0.1s
Pulse Interval	0.01ms-0.9s	0.01ms-20ms	0.1s
Aiming Beam	2mW, 650nm	1mW, 635±10nm	2mW, 640nm
Fiber Diameter	200μm, 300μm and 400μm	200μm, 300μm and 400μm	400μm
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Particular requirements	Comply with IEC 60601-2-22 and IEC 60825-1	Comply with IEC 60601-2-22 and IEC 60825-1	Comply with IEC 60601-2-22 and IEC 60825-1

Patient-contact material	Stainless steel, aluminum, quartz and PP (Polypropylene)	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Unknown
Biocompatibility	Cytotoxicity, ISO 10993-5	Unknown	Unknown
	Sensitization, ISO 10993-10		
	Irritation, ISO 10993-10		

The indications of proposed device is contained by those of predicate device, and proposed device and predicate device are similar in specifications. Although some of specifications of predicate device are not known and the materials are different, both the proposed device and predicate device comply the same standards in electrical safety, EMC and particular requirements, and the proposed device is demonstrated as non-toxic, non-irritating, and non-sensitizing per ISO 10993 series standards. The differences between the proposed device and predicate device do not impact the safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.