DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2016

Zolar Technology & Mfg Co. Inc.
Paul Atkins
Executive Officer
6315 Shawson Drive
Mississauga, L5T 1J2 CA

Re: K162114
Trade/Device Name: Photon, Photon Plus
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: November 17, 2016
Received: November 17, 2016

Dear Paul Atkins:

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" (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 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,

Jennifer R. Stevenson -A

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)*
162114

Device Name
Photon, Photon Plus

Indications for Use *(Describe)*

1. DENTAL SOFT TISSUE INDICATIONS

The indications are identical to the previously cleared predicate systems.

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
- Treatment of aphthous ulcer canker sores and herpetic.
- Vestibuloplasty

2. 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.

3. TOOTH WHITENING INDICATIONS

- Laser Assisted whitening/bleaching of teeth.
- Light activation for bleaching materials for teeth whitening.

4. 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 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.

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"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."

Exhibit # 6

510 (K) Summary

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

The assigned 5l0(k), number is: K162114.

1. Submitter's Identification:

ZOLAR TECHNOLGY & MFG CO. INC.
6315 SHAWSON DRIVE, UNIT # 7-8,
MISSISSAUGA, ON, L5T L5T 1J2, CANADA

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President
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Date Summary Prepared: November 17, 2016

2. Name of the Device:
Photon/Photon Plus

3. Common or Usual Name:
Dental Diode Laser

4. Predicate Device Information:
Biolase Epic 10 510(k) 121286
Cao Precise SHP 510(k) 123443
Photon/Photon Plus 510(k) 122020

5. Device Description:

The Zolar Technology & MFG Co. Inc. Soft Tissue Dental Laser PHOTON/PHOTON PLUS uses a solid state diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to the hand piece that emits the energy to the target site. A visible light (aiming beam) is emitted at the same time to visually assist in identifying the specific treatment location. The Photon/Photon Plus Laser Systems are comprised of a base consol, a detechable delivery system, tips and a wireless footswitch. The Photon/Photon Plus laser is intended to be used by dentist for a variety of oral soft tissue procedures

The original Operator Manual has been revised to reference the additional Pain Indication for use.

6. Indications for Use:

The Photon Series of Dental Diode Lasers are 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:

1. DENTAL SOFT TISSUE INDICATIONS

The indications are identical to the previously cleared predicate systems.

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
- Treatment of aphthous ulcer canker sores and herpetic.
- Vestibuloplasty

2. 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.

3. TOOTH WHITENING INDICATIONS

- Laser Assisted whitening/bleaching of teeth.
- Light activation for bleaching materials for teeth whitening.

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

7. <u>Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:</u>

The subject devices have been tested for thermal, electrical and mechanical safety, as demonstrated in the previously approved clearance 510(k) 122020 and conform to applicable medical device safety standards, IEC 60825-1 and IEC 60601-2-22.

8. <u>Performance Assessment:</u>

The clinical test for the therapeutic heating device indications listed in item 6 of the IFU have been conducted with human subjects and the performance data table demonstrates that the device can increase the skin temperature to 40 – 45 ^{0}c and maintain the effect for at least 10 minutes safely and effectively.

9. <u>Substantial Equivalence:</u>

The purpose of this submission is to consolidate the current Photon/Photon Plus Laser Systems (K122020) with a new Pain Indication.

The Subject Device Photon Dental Diode Laser is of a comparable type and substantially equivalent to the currently marketed and approved Photon/Photon Plus 510(k) 122020, Biolase Epic 510(k) 121286 and Cao Precise SHP 510(k) 123443 in regard to the primary features of soft tissue surgical and minor pain indications for use. The subject device retains similar overall size and weight together with the similar construction materials and performance in addition to equivalent key features. The subject device has the same intended uses as the predicate devices.

The device modifications to include Pain Indications (IFU) do not potentially alter the fundamental scientific technology of the device. Substantial Equivalence for the Photon/Photon Plus Laser Systems has also been determined through comparison to the cleared predicate devices i.e. Biolase Epic 510(k) 121286 and Cao Precise SHP 510(k) 123443. This submission demonstrates that the Photon/Photon Plus Laser systems are safe, as effective and performs as well as the predicate devices indicated above.

10. Conclusion:

The Device modifications do not potentially alter the fundamental scientific technology of the device. Substantial Equivalence for the Photon/Photon Plus Laser Systems has also been determined through the technical comparison to the cleared predicate devices. This submission demonstrates that the Photon/Photon Plus Laser systems are as safe, as effective and performs as well as the predicate devices.

We suggest that there are no significant differences between the subject device, (Photon/Photon Plus) and the predicate devices (Biolase Epic 10/Cao Precise SHP) in terms of indications for use, safety and effectiveness based on electrical, mechanical and environmental test results. With this information and in our opinion the subject device is considered to be substantially equivalent to the predicate devices.

Subject Device Technological Comparison

DEVICE NAME	Photon/Photon Plus	Photon/Photon Plus	Precise SHP	Epic 10
MANUFACTURER	Zolar Technology Inc	Zolar Technology Inc	Cao Group Inc	Biolase Inc
510(K)	162114	122020	123443	121286
DIMENSION	187 -138 -148mm	187 -138 -148mm	139 - 120 - 61mm	145 - 112 - 165mm
WEIGHT	<2.0 kg	<2.0 kg	<2.0 kg	1.1 kg
LASER TYPE	Diode	Diode	Diode	Diode
LASER CLASSIFICATION	4	4	4	4
MAXIMUM POWER	3 watts Photon 10 watts Photon Plus	3 watts Photon 10 watts Photon Plus	3 watts	10 watts
OPERATION MODE	Continuous / Pulse	Continuous / Pulse	Continuous / Pulse	Continuous / Pulse
WAVELENGTH	810 nm Photon 980 nm Photon Plus	810 nm Photon 980 nm Photon Plus	810 nm	940 nm
AUDIBLE NOTIFICATION	Yes	Yes	Yes	Yes
VISUAL NOTIFICATION	Yes	Yes	Yes	Yes
POWER REQUIREMENTS	AC100 ~ 240V 50/60Hz	AC100 ~ 240V 50/60Hz	AC100 ~ 240V 50/60Hz	AC100 ~ 240V 50/60Hz
WIRELESS FOOT PEDAL	Frequency: 2.4 GHz	Frequency: 2.4 GHz	Frequency: 2.4 GHz	Frequency: 2.4 GHz
INDICATIONS FOR USE	Same as those Indications cleared as per K122020, K123443, K121286	Approved Indications as per K122020	Approved Indications as per K123443	Approved Indications as per K121286

Subject Device Indications For Use Comparisons

Predicate	Photon/Photon Plus	Photon/Photon Plus	Precise SHP	Epic 10
510(k) No.	**K162114**	**K122020**	**K123443**	**K121286**
Indications For Use	**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 • Treatment of aphthous ulcer canker sores and herpetic. • Vestibuloplasty.	**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 • Treatment of aphthous ulcer canker sores and herpetic. • Vestibuloplasty	**Dental Soft Tissue Indications** Dentistry and oral soft tissues including: • Incision, excision • Vaporisation • Ablation • Exposure of Unerupted teeth • Fibroma • Frenectomy • Gingival Troughing • Gingivectomy • Gingivoplasty • Hemostasis • Gingival incision and excision hemostasis • Implant exposure • Incision and drainage of abscess • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy • Reduction of gingival hypertrophy • Crown lengthening • Gingival bleeding index • Excisional and incisional biopsies • Treatment of aphthous ulcer canker sores and herpetic. • Vestibuloplasty	**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 • Tissue Retraction for impression • Excisional and incisional biopsies • 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.	**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.	**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. • Laser Soft Tissue Curettage • Distal Wedge	**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) • Laser removal of diseased. Infected, inflamed and necrosed soft tissue within the periodontal pocket. • Laser Soft Tissue Curettage.

Predicate	Photon/Photon Plus	Photon/Photon Plus	Precise SHP	Epic 10
510(k) No.	**K162114**	**K122020**	**K123443**	**K121286**
Indications For Use	**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.	**Tooth Whitening Indications** • Laser Assisted whitening/bleaching of teeth. • Light activation for bleaching materials for teeth whitening.	**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.	**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.