February 22, 2018

LiteCure, LLC
Mr. Curtis Egan
Principal Quality Engineer
Certified Compliance Solutions, Inc.
11665 Avena Place
Suite 203
San Diego, California 92128

Re: K173067
Trade/Device Name: LightForce LTS Model 1000, 1500, 2500, and 4000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: GEX, ILY, PDZ
Dated: September 27, 2017
Received: September 29, 2017

Dear Curtis Egan:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173067

Device Name
LightForce® LTS Model 1000, 1500, 2500, and 4000

Indications for Use *(Describe)*

810 nm and 980 nm wavelength:
The LTS-1000/1500/2500/4000 devices emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; and the temporary relaxation of muscle.

980 nm wavelength:
The LTS-2500/4000 devices are also indicated for use in surgical applications requiring hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, thoracic surgery; and Laser Assisted Lipolysis.

980 nm wavelength:
The LTS-2500/4000 devices are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.)

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

Submitter:	LiteCure, LLC.
Address:	250 Corporate Blvd. Suite B Newark, DE 19702
Phone Number:	(302) 709-0408
FDA Registration #:	3006268867
Contact Person:	Curtis M. Egan, Principal Quality Engineer
Phone Number:	(951) 723 7261
Fax Number:	858-675-8201
Date prepared:	February 15, 2018
Trade name:	LightForce® LTS Model 1000, 1500, 2500, and 4000
Common Name:	Infrared Laser
Classification Name:	Lamp, Infrared, Therapeutic Heating
Product Code:	ILY
Regulation:	21 CFR 890.5500
Classification Name:	Powered Laser Surgical Instrument
Product Code:	GEX
Regulation:	21 CFR 878.4810
Classification Name:	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
Product Code:	PDZ
Regulation:	21 CFR 878.4810

Substantial equivalence claimed to:

For Product Code ILY	
K070516	Power Medic
For Product Code GEX	
K151890	Medical Diode Laser System GBOX-15A/15B, VELAS II-60A/60B/60C
For Product Code PDZ	
K123014	LiteCure Therapy System Model LTS-1500

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Description:

The LTS Product Family of devices are highly reliable, compact and easy to operate medical lasers. The Console Assembly incorporates a touch-screen display panel and a Main Processor PCA. A Software Application, executed in the Main Processor PCA, generates an intuitive, easy to use, Graphical User Interface (GUI) and responds to operator input, via the touch panel, allowing the operator to select from build-in treatment protocols, or adjust and set the system's optical output power and treatment times with minimal effort.

Laser light generated by the Laser Module Sub-Assembly in the Console Assembly is delivered to a subject via a custom designed Beam Delivery Assembly that can be fitted with different Hand Piece Attachments. The various hand piece attachments are designed to allow the operator to deliver, indication specific optimized dose parameters (for example, onychomycosis).

Indications for Use:

810 nm and 980 nm wavelength:
The LTS-1000/1500/2500/4000 devices emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; and the temporary relaxation of muscle.

980 nm wavelength:
The LTS-2500/4000 devices are also indicated for use in surgical applications requiring hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, thoracic surgery; and Laser Assisted Lipolysis.

980 nm wavelength:
The LTS-2500/4000 devices are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.)

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Technological Characteristics:

The underlying technology of the LightForce® LTS Model 1000, 1500, 2500, and 4000 is the same as the predicate devices Power Medic K070516, Medical diode laser system GBOX-15A/15B, VELAS II-60A/60B/60C K151890, and LiteCure Therapy System Model LTS-1500 K123014. The system is based on the same operating principle and control, mechanism to provide the user with the same kind of information and guidance for the same Procedures. The main changes with respect to the predicate device concern the modification to the user interface, safety controls and workflow.

Table 1: Technological Characteristics Compared to Predicate Device ILY:

General Characteristic	LTS-1000 / 1500/ 2500 / 4000	Power Medic K070516
Indication for Use	810 nm and 980 nm wavelength: The LTS-1000/1500/2500/4000 devices emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; and the temporary relaxation of muscle. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use in surgical applications requiring hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, thoracic surgery; and Laser Assisted Lipolysis. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.)	The Power Laser is intended to emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; the temporary relaxation of muscle.
Product Code	ILY	ILY

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General Characteristic	LTS-1000 / 1500/ 2500 / 4000	Power Medic K070516
Laser Type	Diode Laser	Diode Laser
Wavelength	810 nm ± 20 nm AND/OR 980 nm ± 20 nm	808 nm
Output power	5 W at 810 nm and 20 W at 980 nm OR 25 W at 980 nm	300-1500 mW
Dimensions	41.3 cm (L) x 26.4 cm (W) x 25.7 cm (H)	9 in (22.9 cm) (L) x 1.5 in (3.8 cm) (W)
Weight	≤10 kg	7 oz (.2 kg)
Power Supply	100-240 VAC; 50/60 Hz	Battery

Table 2: Technological Characteristics Compared to Predicate Device GEX:

General Characteristic	LTS-1000 / 1500/ 2500 / 4000	GBOX-15A/15B, VELASII-30A/30B, VELAS II-60A/60B/60C K151890
Indication for Use	810 nm and 980 nm wavelength: The LTS-1000/1500/2500/4000 devices emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; and the temporary relaxation of muscle. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use in surgical applications requiring hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, thoracic surgery; and Laser Assisted Lipolysis. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use for the temporary	The “GBOX-15A/15B" are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only). The "VELASII-30A/30B" are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation ,cutting and hemostasis ,or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD),

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General Characteristic	LTS-1000 / 1500/ 2500 / 4000	GBOX-15A/15B, VELASII-30A/30B, VELAS II-60A/60B/60C K151890
	increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.)	Gastroenterology, Head/neck/ENT and Radiology Endovascular coagulation, Oral Surgery and Dental procedures, laser assisted lipolysis. The "VELASII-60A/60B/60C" are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue. Such as: Dermatology, Aesthetics, Plastic Surgery, Vascular Surgery, Podiatry, Endovenous Occlusion of the greater saphenous vein of the thigh in patients with superficial vein reflux.
Product Code	GEX	GEX
Laser Type	Diode Laser	Diode Laser
Wavelength	810 nm ± 20 nm AND/OR 980 nm ± 20 nm	GBOX-15A: 810nm±10nm GBOX-15B: 980nm±10nm VELAS II-30A, VELAS II-60A: 810nm±10nm VELAS II-30B, VELAS II-60B: 980nm±10nm VELAS II-60C: 940nm±10nm
Aiming Beam	Red Diode Laser, 650 nm ± 20 nm, 3.5 mW ± 0.5 mW	Red Diode Laser of 635 nm, Power < 5 mW
Output Power	≤10W | ≤15W | ≤25W | ≤40W	1-15 W | 30 W | 60 W
Pulse width	250, 50, 25, 5, 2.5, 1.0, 0.5, 0.2, 0.1, 0.05 milliseconds, OR per Built-in Protocols	≤2.5s
Repetition Rate	up to 10 KHz	0.2 Hz – 20 KHz
Dimensions	41.3 cm (L) x 26.4 cm (W) x 25.7 cm (H)	245 mm (L) x 215 mm (W) x 315 mm (H)
Weight	≤10 kg	4 kg

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General Characteristic	LTS-1000 / 1500/ 2500 / 4000	GBOX-15A/15B, VELASII-30A/30B, VELAS II-60A/60B/60C K151890
Power Supply	100-240 VAC; 50/60 Hz	GBOX-15A & 15B: 100-240VAC, 200VA, 50-60Hz VELASII-30A, VELAS II -30B: 100-240VAC, 50/60Hz, 350VA VELAS II-60A, VELAS II-60B, VELAS II-60C: 100-240VAC, 50/60Hz, 650VA
Power Requirement	≤400 - ≤600 VA	GBOX-15A & 15B: 100-240VAC, 200VA VELASII-30A, VELAS II -30B: 350VA VELAS II-60A, VELAS II-60B, VELAS II-60C: 650VA

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Table 3: Technological Characteristics Compared to Predicate Device PDZ:

General Characteristic	LTS-1000 / 1500/ 2500 / 4000	LTS-1500 K123014
Indication for Use	810 nm and 980 nm wavelength: The LTS-1000/1500/2500/4000 devices emit energy in the visible and near infrared spectrum to provide 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; the temporary increase in local blood circulation; and the temporary relaxation of muscle. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use in surgical applications requiring hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, thoracic surgery; and Laser Assisted Lipolysis. 980 nm wavelength: The LTS-2500/4000 devices are also indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.)	810 nm and 980 nm: LiteCure Therapy System, Model LTS-1500 is indicated for emitting energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation. 980 nm: LiteCure Therapy System, Model LTS-1500 is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).
Product Code	PDZ	PDZ
Laser Type	Diode Laser	Diode Laser
Wavelength	810 nm ± 20 nm AND/OR 980 nm ± 20 nm	810 nm ± 20 nm AND/OR 980 nm ± 20 nm
Aiming Beam	Red Diode Laser, 650 nm ± 20 nm, 3.5 mW ± 0.5 mW	Red Diode Laser, 650 nm ± 20 nm, 3.5 mW ± 0.5 mW
Output Power	≤10W | ≤15W | ≤25W | ≤40W	≤25W
Pulse Duration	250, 50, 25, 5, 2.5, 1.0, 0.5, 0.2, 0.1, 0.05 milliseconds, OR per Built-in Protocols	250, 50, 25, 5, 2.5, 1.0, 0.5, 0.2, 0.1, 0.05 milliseconds, OR per Built-in Protocols
Repetition Rate	up to 10 KHz	up to 10 KHz

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General Characteristic	LTS-1000 / 1500/ 2500 / 4000	LTS-1500 K123014
Dimensions	41.3 cm (L) x 26.4 cm (W) x 25.7 cm (H)	41.3 cm (L) x 26.4 cm (W) x 25.7 cm (H)
Weight	≤10 kg	≤10 kg

Verification and Validation Documentation:

The LightForce® LTS Model 1000, 1500, 2500, and 4000 tests include verification and validation performance testing as well as usability testing to demonstrate no new safety and efficacy issues are raised with this new device. Analyses demonstrate that system accuracy and performance are adequate for the established intended use. In conclusion, the modified LightForce® LTS Model 1000, 1500, 2500, and 4000 is substantially equivalent to the predicate devices.

Conclusion:

This performance of the LightForce® LTS Model 1000, 1500, 2500, and 4000 is substantially equivalent to that of the PREDICATE Systems Power Medic K070516, Medical diode laser system GBOX-15A/15B, VELAS II-60A/60B/60C K151890, and LiteCure Therapy System Model LTS-1500 K123014.

We believe that the documentation and objective evidence provided demonstrates that the LightForce® LTS Model 1000, 1500, 2500, and 4000 has been demonstrated to be substantially equivalent to the predicate devices and raises no new concerns related to safety or efficacy.