DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 24, 2017

Lutronic Corporation
Jhung Vojir
VP, Quality And Regulatory Affairs
6 Neshaminy Interplex,
Suite 100
Trevose, Pennsylvania 19053

Re: K163196
Trade/Device Name: ACTION II 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, ONG
Dated: May 12, 2016
Received: May 15, 2016

Dear Jhung Vojir:

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 -S

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)*
K163196

Device Name
ACTION II Laser System

Indications for Use *(Describe)*
The ACTION II Laser System is indicated for: coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

The ACTION II Laser Module Fractional Handpiece is indicated for: use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: Dermatology and Plastic Surgery: skin resurfacing treatment of wrinkles; epidermal nevi; telangiectasia; spider veins; actinic chelitis; keloids; verrucae; skin tags; anal tags; keratoses; scar revision (including acne scars).

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.

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510(k) Summary
Lutronic ACTION II Laser System

This 510(k) Summary is being submitted in accordance with 21 CFR § 807.92.

1. Submitter's Information

Applicant: Lutronic Corporation

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VP of Quality and Regulatory Affairs

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Email: jvojir@lutronic.com

Date Prepared: May 22, 2017

2. Device Information

Trade Name: ACTION II Laser System

Common Name: Medical Laser System

Classification Name: Powered Laser Surgical Instrument
Product Code: GEX, ONG
Panel: General and Plastic Surgery

3. Predicate Devices

510(K) Number	K153229	K150140
Company Name	Bios S.R.L.	Asclepion Laser Technologies, GmbH

Device Name	Superbium	MCL 31 Dermablate
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class	II	II
Product Code	GEX, ONG, ONF	GEX

4. Device Description

The ACTION II Laser System produces a pulsed beam of coherent near-infrared (2940 nm) light upon activation by a footswitch. The beam is then directed to the treatment zone by means of an articulated arm coupled to a handpiece. An integrated LCD touch screen gives the user control over the necessary laser system parameters. An aiming beam is coincident with the 2940 nm main laser beam.

5. Indications for Use

The ACTION II Laser System is indicated for: coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

The ACTION II Laser Module Fractional Handpiece is indicated for: use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: Dermatology and Plastic Surgery: skin resurfacing treatment of wrinkles; epidermal nevi; telangiectasia; spider veins; actinic chelitis; keloids; verrucae; skin tags; anal tags; keratoses; scar revision (including acne scars).

6. Substantial Equivalence

The ACTION II Laser System is substantially equivalent to the legally marketed Superbium and MCL 31 Dermablate.

Manufacturer	**Lutronic Corporation**	**Bios S.R.L.**	**Asclepion Laser Technologies, GmbH**
Device Name	**ACTION II Laser System**	**Superbium (Primary Predicate)**	**MCL 31 Dermablate**
510(k) #	**K163196**	**K153229**	**K150140**
Indications for Use	The ACTION II Laser System is indicated for: coagulation, vaporization, ablation or cutting of soft	The 2940 nm Er:YAG Laser Module handpiece is indicated for: Coagulation, vaporization, ablation or cutting of soft tissue	The MCL 31 Dermablate laser system is intended for coagulation, vaporization, ablation or cutting of soft

	tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes). The ACTION II Laser Module Fractional Handpieces are indicated for: use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: Dermatology and Plastic Surgery: skin resurfacing treatment of wrinkles; epidermal nevi; telangiectasia; spider veins; actinic chelitis; keloids; verrucae; skin tags; anal tags; keratoses; scar revision (including acne scars).	(skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes). Laser skin resurfacing procedures for the treatment of: • Acne scars • Wrinkles The 2940 nm Er:YAG Fractional tips are indicated for: use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: Dermatology and Plastic Surgery: skin resurfacing treatment of wrinkles; epidermal nevi; telangiectasia; spider veins; actinic chelitis; keloids; verrucae; skin tags; anal tags; keratoses; scar revision (including acne scars).	tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX 21 CFR 878.4810
Laser Source	Er: YAG	Er: YAG	Er: YAG
Wavelength	2940 nm	2940 nm	2940 nm
Weight of Laser	86.5 kg	35 kg	75 kg
Power max	22W	12 W	20W
Energy max	2.2 J	2.5 J	2.5 J
Pulse Width	200 – 300 µs	200-2200 µs	100-1000 µs
Spot Size	1-14 mm	1 - 9 mm	1-12 mm
Frequency max	20 Hz	5 Hz	20 Hz
Fluence max	280 J/cm^2 (spot 1 mm)	316 J/cm2 (spot 1 mm)	318 J/cm2 (spot 1 mm)
Module Fractional Handpiece			
Beam Diameter (dots)	9x9	7x7, 9x9	
Fluence	13 mJ/dot	13 mJ/dot	
Number of Dots	81 dots/cm^2	81 dots/cm^2 (9x9)	
Max Frequency	5 Hz	5 Hz	
Max Power	12 W	12 W	

7. Non-Clinical Performance Data

The ACTION II Laser System complies with the following standards:
IEC 60601-1 2005 + 1 (2006) + CORR 2 (2007) + AM1 (2012) or IEC 60601-1 2012. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2 (Third Edition, 2007), Medical Electrical Equipment-Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility.

IEC 60601-2-22 Third Edition 2007-05 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

8. Clinical Performance Data

None.

9. Conclusion

The ACTION II Laser System and the legally marketed Superbium cleared under 510(k) number K153229 have the same intended use and Indications for Use statement. Any technological differences between the ACTION II Laser System and its predicate devices are considered minor and do not raise any different types of questions regarding safety or effectiveness when used according to its intended use. The ACTION II Laser System is substantially equivalent to the predicate devices.