



Food and Drug Administration
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December 30, 2015

Biorenew Labs, LLC
c/o Susan Anthony-Dewet
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, IA 52241

Re: K152889

Trade/Device Name: Sonilase Blue Blue, Sonilase Blue-Clean, Sonilase UV-Clean 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: OLP
Dated: September 29, 2015
Received: September 30, 2015

Dear Ms. Anthony-Dewet:

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,

David Krause -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

Indications for Use

510(k) Number (if known)

K152889

Device Name

Sonilase Blue, Sonilase Blue-UV Clean, and Sonilase Blue-UV Clean Plus

Indications for Use (Describe)

The Sonilase Blue is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

The Sonilase Blue-UV Clean is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

The Sonilase Blue-UV Clean Plus is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

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

K152889

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 878.4810.

Submission Date: September 16, 2015

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthony-DeWet
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For Specifications Developer: Biorenew Labs, LLC

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2. General Information

2.1 Classification Name: Light Based Over-The-Counter Powered Light Based Laser For Acne

2.2 Common/Usual Name: Sonilase Blue, Sonilase Blue-Clean, and Sonilase UV-Clean Plus
Light Devices

2.3 Proprietary Names: Sonilase Blue, Sonilase Blue- Clean, and Sonilase UV-Clean Plus Light
Devices

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OLP

3. Device Description:

The Sonilase Blue, Sonilase Blue- Clean, and Sonilase Blue-UV Clean Plus are modular system devices that offer blue light therapy for the treatment of mild to moderate acne vulgaris.

The Sonilase Blue device components include the handheld unit containing the LED module with 3 (415nm) LEDs , attachable clear plastic lens cover, an adjunct attachable cleansing brush head, recharging stand, 7.4 v LI-ION BATTERY, 9V UL approved power supply and goggles.

The Sonilase Blue-Clean device components include the handheld unit containing the LED module with 3 blue LEDs (415nm) attachable opaque lens cover, an adjunct attachable cleansing brush head, recharging stand, 7.4 v LI-ION BATTERY, 9V UL approved power supply and goggles.

The Sonilase Blue-UV Clean Plus device components include the handheld unit containing the LED module with 3 blue LEDs (415nm) and 3 UV sanitizing LEDs , attachable opaque lens cover, a detachable cleansing brush head, recharging stand, 7.4 v LI-ION BATTERY, 9V UL approved power supply and goggles.

The Sonilase Blue, Sonilase Blue-UV Clean, and Sonilase Blue-UV Clean Plus devices operate by a cordless system drawing upon their 7.4V rechargeable LI-ION battery to deliver the treatment.

The Sonilase Blue, Sonilase Blue-Clean, and Sonilase Blue-UV Clean Plus utilize blue light at 415 nm +/- 5nm.

The Sonilase Blue is applied directly to the skin to ensure consistent administration of light during each treatment.

The Sonilase Blue-Clean and Sonilase Blue-UV Clean Plus are applied to the skin with the cleansing brush still attached, but the amount of treatment energy (Dose) delivered to the skin is the same.

The Sonilase Blue, Sonilase Blue-Clean, and Sonilase Blue-UV Clean Plus have a skin sensor that will not allow the device to illuminate unless it is in contact with the skin as a safety feature.

The Sonilase Blue, Sonilase Blue- Clean, and Sonilase Blue-UV Clean Plus devices do not contain any user serviceable components. The devices are sold as Over the Counter (OTC).

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4. Indications / Intended Use:

The Sonilase Blue is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

The Sonilase Blue- Clean is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

The Sonilase Blue-UV Clean Plus is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris.

Rx or OTC:

The Sonilase Blue series of light device are Over the Counter (OTC) devices. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate device is OTC.

5. Predicate Device:

These devices are substantially equivalent to the following predicate devices, which are currently in safe and effective commerce:

Primary Predicate Device: K121435 – Silk’n Blue (Home Skinovations LTD)

Secondary Predicate Device: K124042 – Tanda Mini Skincare System (Syneron Beauty Inc.)

Predicate Chart

Device	Silk ‘N Blue Home Skinovations LTD. K121435 A Predicate Device	Tanda Mini Skincare System Syneron Beauty Inc. K124042 A Predicate Device	Sonilase Blue-Acne Model-SL113B Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-Clean Model-SL113BC Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-UV Clean Plus Model-SL113BUV+ Biorenew Labs, LLC K152889 This Submission
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Device	Silk 'N Blue Home Skinovations LTD. K121435 A Predicate Device	Tanda Mini Skincare System Syneron Beauty Inc. K124042 A Predicate Device	Sonilase Blue-Acne Model-SL113B Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-Clean Model-SL113BC Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-UV Clean Plus Model-SL113BUV+ Biorenew Labs, LLC K152889 This Submission
Indications		The Tanda Mini Skincare System is generally indicated to treat dermatological conditions. Specifically, blue light modules are indicated to treat mild to moderate inflammatory acne.	The Sonilase Blue is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris..	The Sonilase Blue-Clean is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris	The Sonilase Blue-UV Clean Plus is a hand held OTC device intended to emit energy in the blue region of the light spectrum for use in the treatment of mild to moderate acne vulgaris
Handheld	Yes	Yes	Yes	Yes	Yes
Wavelength	415 nm +/- 15nm	414 nm +/- 6nm	415 nm +/- 5nm	415 nm +/-5nm	415 nm +/-5nm
Modes	On/Off	On/Off	On/Off	On/Off	On/Off
Blue power source	LEDs	LEDs	LEDs	LEDs	LEDs
Energy Source	24 LEDs . Over 7 cm2	7 LEDs. Unknown area.	3 LEDs. Over 9.6 cm2	3 LEDs. Over 9.6 cm2	3 LEDs. Over 9.6 cm2
Energy Level	50 mW/cm2	22.4 mW/cm2	50 mW/cm2	50 mW/cm2	50 mW/cm2
Method of Delivery	Blue light treatment administered through stainless steel treatment head containing LED	Blue light treatment administered through treatment head.	Blue light treatment administered through treatment head.	Blue light treatment administered through lens or brush.	Blue light treatment administered through lens or brush.

Device	Silk 'N Blue Home Skinovations LTD. K121435 A Predicate Device	Tanda Mini Skincare System Syneron Beauty Inc. K124042 A Predicate Device	Sonilase Blue-Acne Model-SL113B Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-Clean Model-SL113BC Biorenew Labs, LLC K152889 This Submission	Sonilase Blue-UV Clean Plus Model-SL113BUV+ Biorenew Labs, LLC K152889 This Submission
	array.				
Power Supply	Unknown	One 9v rechargeable alkaline battery	One 7.4v rechargeable LI-ION BATTERY	One 7.4v rechargeable LI-ION BATTERY	One 7.4v rechargeable LI-ION BATTERY
Treatment Time	* 3-4 minutes daily, for 3-7 weeks	*2 minutes, 3 times per day.	4 minutes per area, daily.	4 minutes per area, daily.	4 minutes per area, daily.
Target Population	Individuals with mild to moderate acne	Individuals with mild to moderate acne	Individuals with mild to moderate acne	Individuals with mild to moderate acne	Individuals with mild to moderate acne
Location for Use	OTC	OTC	OTC	OTC	OTC

Summary of the technological characteristics of the device compared to predicate device:

1. Has the same intended use as the predicate (i.e., Treatment of mild to moderate acne vulgaris);
2. Has the same output (i.e., 50 mW/cm²) as the predicate;
3. Utilizes the same wavelength (i.e., 415 nm) as the predicate device;
4. Utilizes the same standard dose (i.e., 12J/cm²) as the predicate device;

The Sonilase Blue Light Devices and the above referenced predicate devices are Over the Counter Devices used to treat mild to moderate acne vulgaris as defined in 21 CFR § 878.4810. These devices utilize blue diodes at 415nm to provide narrow bands of light energy to treat acne vulgaris. The performance achieved by these devices is similar with equal power output. The devices are handheld, and intended to be placed directly on the skin. They are manufactured out of similar materials. Based upon comparison to the predicate device, the Sonilase Blue Light Devices have the same intended uses, with similar technological characteristics as the predicate device. The system performs as intended and does not raise any new safety or effectiveness issues.

6. Technological Characteristics

The Sonilase Blue light delivery system used for applying therapy for the treatment of acne vulgaris, by emitting at least 50 mW/cm² of blue (415 nm +/- 5nm) light via an electric light emitting diodes [LEDs] energy source. There are 3 blue LEDs in the head. The LED head size is 9.6cm².

The Sonilase Blue- Clean light delivery system used for applying therapy for the treatment of acne vulgaris, by emitting at least 50 mW/cm² of blue (415 nm +/- 5nm) light via an electric light emitting diodes [LEDs] energy source, transmitted through the cleansing brush head. There are 3 blue LEDs in the head. The LED head size is 9.6cm².

The Sonilase Blue-UV Clean Plus light delivery system used for applying therapy for the treatment of acne vulgaris, by emitting at least 50 mW/cm² of blue (415 nm +/- 5nm) light via an electric light emitting diodes [LEDs] energy source, transmitted through the cleansing brush head. There are 3 blue LEDs in the head. The LED head size is 9.6cm².

The Sonilase Blue, Sonilase Blue-Clean, and Sonilase Blue-UV Clean Plus devices are not intended for ocular applications or direct eye exposure.

7. Performance Testing and Standards:

Testing of the Sonilase Blue series of devices included functional performance testing, software validation testing and user safety testing.

The results of this testing are as follows:

Conforms to international consensus standards:

ELECTRICAL SAFETY:**Recognition Number 19-4:**

- IEC/EN 60601-1:2005 Edition 3/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))

PERFORMANCE:**Recognition Number 12-242:**

- IEC 60601-2-57 Edition 1.0 2011-01, Medical Electrical Equipment -- Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended for Therapeutic Diagnostic Monitoring and Cosmetic/Aesthetic Use (Radiology)

EMC:**Recognition Number 19-1:**

- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General II (ES/EMC))

The Sonilase Blue series of device's software was tested and validated in accordance with FDA's "*Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.*"

A Usability/Label Comprehension Study was conducted with 39 participants.

The results of the study found that:

100% of the participants were able to comprehend the labeling.

97% of the participants were able to use the device successfully.

User Safety testing reflects device can be used in a safe and effective manner.

9. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, and treatment regimes the manufacturer believes that no significant differences exist between the device and the predicate device. Therefore substantial equivalency is requested.