February 23, 2021

Global Med Systems SL
% Kevin Morningstar
Senior Consultant
Morningstar Consulting Group
20319 E Costilla Ave
Centennial, Colorado 80016

Re: K203804
Trade/Device Name: Global Med Systems Milesman Compact Laser
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: December 21, 2020
Received: December 28, 2020

Dear Kevin Morningstar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203804

Device Name

Global Med Systems Milesman Compact Laser

Indications for Use *(Describe)*

The Global Med Systems Milesman Compact Laser is intended for use in dermatological and general surgical procedures including hair removal and permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. It is intended for use on all skin types (Fitzpatrick skin types 1-VI), including tanned skin.

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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Compact 510(k) Summary

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Date Prepared: February 14, 2021

II. DEVICE

Name of Device: Global Med Systems Milesman Compact Laser
Common or Usual Name: Powered Laser Surgical Instrument
Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number: 21 CFR 878.4810
Regulatory Class: Class II
Product Code: GEX

III. PREDICATE DEVICE

K073300 Milesman Premium Diode Laser System by Milesman S.L.

This predicate has not been subject to a design-related recall.

Reference Device: K140009 Alma Soprano™ Laser by Alma Lasers Ltd.

IV. DEVICE DESCRIPTION

The Global Med Systems Milesman Compact Laser delivers pulsed laser energy at 810 nm to the surface of the skin using a handpiece which contains the laser diodes. The Milesman Compact consists of the following components:

1. The main console unit
2. Handpiece
3. Umbilical (between main console and handpiece)
4. Footswitch

The system is operated using the touch screen on top of the main console unit. Firing of the laser is controlled with either the footswitch or the trigger on the handpiece.

During hair removal, the laser emits a wavelength of light that is absorbed by the pigment (melanin) in the hair. The light energy is converted to heat, which damages the tube-shaped sacs within the skin (hair follicles) that produce the hair. This damage inhibits or delays future hair growth.

The face of the hand piece which comes into contact with skin is actively cooled with a circulating coolant fluid.

V. INDICATIONS FOR USE

The Global Med Systems Milesman Compact Laser is intended for use in dermatological and general surgical procedures including hair removal and permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. It is intended for use on all skin types (Fitzpatrick skin types 1-VI), including tanned skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

	Alma Soprano* (Reference) – K140009	**Milesman Premium (Predicate) - K073300**	**Milesman Compact (Subject) – K203804**	**Comparison Remarks (subject to predicate/reference)**
Trade/Proprietary Name	The Modified Alma Lasers XL™ Family of Multi-Application and Multi- Technology Platforms [Soprano^{XL} Soprano^{XLi} and Soprano^{ICE}]	Milesman Premium Pulsed Diode Array Laser System	Milesman Compact Diode Laser System	Similar (predicate and subject device are made by the same company; Compact is a smaller lighter version of the Premium, made possible by using the latest available laser diode technology)
Generic/Common Name	Hair removal laser	Hair removal laser	Hair removal laser	Identical
Classification Name	Laser Instrument, Surgical, Powered	Laser Instrument, Surgical, Powered	Laser Instrument, Surgical, Powered	Identical
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	Laser surgical instrument for use in general, and plastic surgery and in dermatology	Identical
Regulatory Class	Class II	Class II	Class II	Identical
Product Code	GEX	GEX	GEX	Identical
Regulation Number	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	Identical
Review Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Identical
Indications for use	The Hair Removal (HR) and Super Hair Removal (SHR) Mode is intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen. The treatment of benign vascular lesions (The laser blanch (LB) mode). Use on all skin types (Fitzpatrick I-VI) including tanned skin (HR, SHR and LB modes)	The Milesman Premium Pulsed Diode Array Laser System is intended for use in general and plastic surgery and dermatology procedures for the treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions and treatment for pseudofolliculitis barbae. The Milesman Premium is also used for removal of unwanted hair, permanent hair reduction and the treatment of benign pigmented lesions and leg veins in all skin types (Fitzpatrick I-VI), including tanned skin.	The Global Med Systems Milesman Compact Laser is intended for use in dermatological and general surgical procedures including hair removal and permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. It is intended for use on all skin types (Fitzpatrick skin types 1-VI), including tanned skin.	Similar but narrower in scope (subject device indication does not mention vascular lesions, benign pigmented lesions or leg veins as the predicate does; subject device indication includes the same “permanent” definition that the reference device does whereas predicate does not; predicate mentions specific medical conditions whereas subject and reference devices do not)
Light/Laser Source	Diode	Diode	Diode	Identical

Global Med Systems Milesman Compact Laser 510(k) K203804

	Alma Soprano* (Reference) – K140009	Milesman Premium (Predicate) - K073300	Milesman Compact (Subject) – K203804	Comparison Remarks (subject to predicate/reference)
Wavelength	810 nm	810 nm (nominal)	810 nm	Identical
Repetition rate	.5-3 Hz ("HR" or "hair removal" mode) 5-10 Hz ("SHR" or "super hair removal" mode)	1-3 Hz	1-10 Hz	Similar (subject device is more comparable to the reference device than the predicate when combining predicate's "HR" mode and "SHR" mode)
Fluence - Energy Density	2-120 J/cm^2 ("HR" mode) 2-20 J/cm^2 ("SHR" mode)	10 – 100 J/cm^2	12-30 J/cm^2	Similar (subject device has a narrower range of values than either the predicate or reference (in "HR" mode) device)
Maximum fluence utilized per treatment protocols	40 J/cm^2	40 J/cm^2	30 J/cm^2	Similar (subject device has a lower maximum value than either the predicate or reference device)
Pulse Duration	3.3-200 ms	5 – 400 ms	5 to 150 ms	Similar (Reference device provides the greatest range of values; subject device provides the narrowest range)
Spot Size	12 x 10 mm	10 x 10 mm	10 x 10 mm	Identical (subject device compared to predicate; reference device has larger spot size)
Maximum average power	100 W	120 W	120 W	Similar (subject device and predicate are identical but both are 20% greater than the reference device)
Peak Power	Unknown	2000 W	2000 W	Identical (subject device compared to predicate)
Tissue Cooling	Contact	Contact	Contact	Identical
How Supplied	Non-sterile - cleanable	Non-sterile - cleanable	Non-sterile - cleanable	Identical
Exposure Indicator	Audible & visual indicator	Audible & visual indicator	Audible & visual indicator	Identical
User Interface	Touch screen	Touch Screen	Touch Screen	Identical
Laser Dimension	53 cm x 57 cm x 120 cm	40 cm x 50 cm x 36 cm	35 cm x 42 cm x 23 cm	Different (the subject device is somewhat smaller than the predicate; both are smaller than the reference device)
Weight	50 kg. / 110 lbs.	45 kg. / 120.64 lbs.	9 kg. / 19 lbs.	Different (the subject device is considerably lighter than both the predicate and reference devices)

* 810 nm diode laser version of the Soprano™ with 1.2 cm^2 laser spot size, in either HR (hair removal) or SHR (super hair removal) mode

VII. PERFORMANCE DATA

The following performance data on the current design were provided in support of the substantial equivalence determination.

IEC 60825-1 Edition 3.0 2014-05 Safety of laser products – Part 1: Equipment classification and requirements
IEC 60601-2-22 Medical electrical equipment - Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Biocompatibility testing
Compact Biocompatibility report for in vitro cytoxicity
Compact Biocompatibility report for Dermal Irritation
Compact Biocompatibility report for Skin Sensizitation

Electrical safety and electromagnetic compatibility (EMC)
IEC 60601-1:2005 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 disturbances — Requirements and tests

Note: A gap analysis was conducted to demonstrate compliance with the FDA-recognized standard for electrical safety (AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012) because testing to the non-FDA-recognized standard IEC 60601-1:2005 was conducted.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Software verification and validation testing was performed at both the unit level and integrated level using written protocols. The written protocols include a description of the acceptance criteria, which in most cases is taken as defined by the SRS (Software Requirements Specification). Test results are documented in test reports. Verification testing exercised software functionality by comparing actual outputs to those expected in response to pre-established inputs. Validation testing was done at the system level by operating the device in simulated use scenarios. A traceability matrix was used to account for each software requirement in the SRS to ensure testing thoroughness. For test failures, the software under test was analyzed and rewritten and the software test repeated. All software successfully passed verification and validation testing.

Animal Study
An animal study was not conducted.

Clinical Studies
Clinical testing was not conducted.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and design verification and validation demonstrate that the Global Med Systems Milesman Compact device performs as intended in the specified use conditions. The Global Med Systems Milesman Compact device performs comparably to the predicate device (and reference device) that was marketed for the same intended use and shares the same or similar indications for use, similar design features, and functional features with, and thus is as safe, as effective, and performs as well as the legally marketed predicate devices.

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