November 19, 2019

GME German Medical Engineering GmbH
% Mike Johnson
Consultant
Philosopher's River LLC
P O Box 106
Willow Creek, Montana 59760

Re: K192269
Trade/Device Name: TwinScan 808/755 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
Dated: August 6, 2019
Received: August 21, 2019

Dear Mike Johnson:

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); 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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192269

Device Name
TwinScan 808/755 Laser System

Indications for Use *(Describe)*
The GME TwinScan 808/755 Laser System is indicated for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.

The GME TwinScan 808/755 Laser System is intended to be used on all skin types (Fitzpatrick I-VI).

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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K192269

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 08-08-2019 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

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B. Contact Information

Philosopher's River llc

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Willow Creek, MT 59760

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Fax: 406 209 3039

Contact person: Mike Johnson M.D.

mike@philosophersriver.com

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *TwinScan 808/755 Laser System*
Device Common Name: Laser Instrument for Dermatology
Classification Name: Laser Instrument, Surgical Powered 21 CFR 878.4810
Product Code: GEX
Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *TwinScan 808/755 Laser System* uses similar technology and physical output characteristics as the following predicate devices*:*
K180518 GME *LinScan Lite 808 System*, and
K143519 Asclepion *MeDioStar NEXT*

E. Device Description [21 CFR 807.92(a)(4)]

The *TwinScan 808/755 Laser System* is a diode laser designed to be used in Dermatological practice for stable, long term hair reduction.

The *TwinScan 808/755 Laser System* consists of a base unit (touch screen, mains switch, key switch, Emergency Stop button) that controls an applicator unit. The applicator unit contains the diode laser and scanner. The device may be configured with 808 nm or 755 nm Applicators, in two treatment area sizes, at the factory.

The *TwinScan 808/755 Laser System* includes the following accessories: Power cord, foot switch, laser protective goggles, applicator holder, and coolant refill kit. A cooled sapphire is the only patient contacting part of the system. There are no single use parts in the *TwinScan 808/755 Laser System*.

Principle of Operation: The laser light is converted to heat when it strikes a chromophore (pigment). The heat denatures the protein of the chromophore (in this case, hair follicle). Specifically, the hair follicle contains pigment and reacts to laser light by heating. Heating denatures proteins in the hair follicle, retarding hair growth.

F. Device Specifications and Comparison to Predicates [21 CFR 807.92(a)(6)]

The GME *TwinScan 808/755 Laser System* is compared to the predicates

- GME *LinScan Lite 808 System* K180518
- Asclepion *MeDioStar* K143519

The indications for use and classification for the *TwinScan 808/755 Laser System* are equivalent to the predicates. Below is a comparison table of specifications.

Characteristic	GME TwinScan 808/755 Laser System "TwinScan"	GME LinScan Lite 808 Laser System "LinScan 808"	Asclepion MeDioStar NeXT PRO XL "MeDioStar"
Applicable 510(k)s	NA	K180518	K143519

Panel/ **Product Code/ Regulation Number**	General and Plastic Surgery GEX 21 CFR 878.4810	General and Plastic Surgery GEX 21 CFR 878.4810	General and Plastic Surgery GEX 21 CFR 878.4810
Indications for Use Statement	The GME TwinScan 808/755 Laser System is indicated for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime. The GME TwinScan 808/755 Laser System is intended to be used on all skin types (Fitzpatrick I-VI).	The GME LinScan Lite 808 Laser System is indicated for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime. The GME LinScan Lite 808 System is intended to be used on all skin types (Fitzpatrick I-VI).	The MeDioStar NeXT Family laser system is intended for hair removal and permanent hair reduction defined as reduced hair growth with or without maintenance when measured at 6, 9 and 12 months. The MeDioStar NeXT Family laser system is intended for the treatment of benign vascular lesions. The MeDioStar NeXT Family laser system is intended for the treatment of benign pigmented lesions.
Classification	Class IV	Class IV	Class IV
Common Name	Pulsed diode laser	Pulsed diode laser	Pulsed diode laser
Mechanism of Action	Heats chromophores (pigments) and water in the skin through the absorption of light. The heating denatures proteins of the hair follicle	Heats chromophores (pigments) and water in the skin through the absorption of light. The heating denatures proteins of the hair follicle.	Heats chromophores (pigments) and water in the skin through the absorption of light. The heating denatures proteins of the hair follicle.

Characteristic	GME TwinScan 808/755 Laser System "TwinScan"	GME LinScan Lite 808 "LinScan Lite 808"	Asclepion MeDioStar NeXT PRO XL "MeDioStar"
Applicable 510(k)s	NA	K180518	K143519
Mode of Operation	Pulsed diode laser	Pulsed diode laser	Pulsed diode laser

Light Source	Laser diode	Laser diode	Laser diode
Light Delivery	Laser and scanner are in the Applicator handpiece	Laser and scanner are in the Applicator handpiece	Laser is in handpiece
Cooling of Skin	Sapphire provides contact cooling	Sapphire provides contact cooling.	Sapphire provides contact cooling.
Treatment Area Size	f-hp - applicator: 15 x 13 mm, 15 x 50 mm or 15 x 25 mm p-hp - applicator: 10 x 25 mm, 10 x 13 mm	10 x 25 mm, 10 x 13 mm	14 x 10 mm, 4 x 3 mm, 8 x 6 mm, 30 x 10 mm, 38 x 24 mm
Peak Power	Up to 300 W	Up to 150W	2400W
Power Density	See wavelength comparison	See wavelength comparison	See wavelength comparison
Fluence (Energy Density per Flash)	See wavelength comparison	See wavelength comparison	See wavelength comparison
Pulse Duration	4-100ms	4-100ms	Up to 400ms
Repetition Rate	up to 10 Hz	up to 2 Hz	4 to 12 Hz
System Cooling	Self contained, closed water circulation system	Self contained, closed water circulation system	Self contained, closed water circulation system
Wavelength	755 nm or 808 nm	808 nm	755 nm, 808 nm or 940 nm
Beam Mode	Multimode	Multimode	Multimode
Aiming Beam	None	None	None
Controls	Footswitch or handswitch	Footswitch or handswitch	Footswitch or handswitch
Electrical Requirements	100 V-240 V @ 50/60 Hz, max.1750 W	100V-240V @ 50/60Hz, max. 900W	100 -240 VAC, 50/60 Hz, max. 1500W
Power Calibration Method	Diode current calibrated by external power ruler	Diode current calibrated by external power ruler	Diode current calibrated by external power ruler

Sterilization Aspects	Applicator is cleaned / disinfected between patients.	Applicator is cleaned / disinfected between patients.	Applicator is cleaned / disinfected between patients.
Pulse Formation	CW current switched on / off	CW current switched on / off	CW current switched on / off
Pulse Train Duration	4 ms – 100 ms	4 ms – 100 ms	Up to 400 ms
Beam Diameter	f-hp applicator: 1mm x 15mm p-hp applicator: 0.75 mm x 10 mm	0.75 mm x 10 mm	14 x 10 mm, 4 x 3 mm, 8 x 6 mm, 30 x 10 mm, 38 x 24 mm
Duty Cycle	< 100%	< 100%	< 100%
Pulse Controls	fluence, pulse duration	fluence, pulse duration	fluence, pulse duration
Display	Touch Screen Control Panel	Touch Screen Control Panel	Touch Screen Control Panel

Characteristic	GME TwinScan 808/755 Laser System "TwinScan"	GME LinScan Lite 808 "LinScan 808"	Asclepion MeDioStar NeXT PRO XL "MeDioStar"
Applicable 510(k)s	NA	K180518	K143519
808 nm Predicate		X	
808 Beam Size	f-hp applicator: 1mm x 15mm (0.15 cm^2) p-hp applicator: 0.75 mm x 10 mm (0.075 cm^2)	0.75 mm x 10 mm	NA
808 Power Density	Up to 2000 W/cm²	Up to 2000 W/cm²	NA
808 Treatment Area Size	f-hp – 808 applicator: 15 x 13 mm (1.95 cm^2) 15 x 25 mm (3.75 cm^2) 15 x 50 mm (7.5 cm^2) p-hp - 808 applicator: 10 x 25 mm (2.5 cm^2) 10 x 13 mm (1.3 cm^2)	10 x 13 mm 10 x 25 mm	NA

808 Peak Power	Up to 300 W	Up to 150W	NA
808 Fluence	4-100 J/cm2	4-100 J/cm2	NA
755 Predicate		NA	X
755 Beam Size	f-hp applicator: 1mm x 15mm (0.15 cm^2) p-hp applicator: 0.75 mm x 10 mm (0.075 cm^2)	NA	1.4 cm^2
755 Power Density	f-hp = 150W/0.15cm^2 =1000 W/cm^2 p-hp = 75W/0.075 = 1000 W/cm^2	NA	ALX handpiece 2400W/1.4cm^2 =1714 W/cm^2
755 Treatment Area Size	f-hp – 755 applicator: 15 x 13 mm (1.95 cm^2) 15 x 25 mm (3.75 cm^2) 15 x 50 mm (7.5 cm^2) p-hp - 755 applicator: 10 x 25 mm (2.5 cm^2) 10 x 13 mm (1.3 cm^2)	NA	1.4 cm^2
755 Peak Power	Up to 150 W	NA	2400W
755 Fluence	4-50 J/cm²	NA	Up to 35 J/cm²

G. Indications for Use [21 CFR 807.92(a)(5)]

The GME TwinScan 808/755 Laser System is indicated for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.

The GME TwinScan 808/755 Laser System is intended to be used on all skin types (Fitzpatrick I-VI).

H. Performance Data [21 CFR 807.92(b)(2)]

The Guidance Document, Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice 56) January 19, 2018 was used. Testing reports for IEC 60825-1 and IEC 60601-2-22 were submitted. Testing reports for IEC 60601-1 and

IEC 60601-1-2 were also submitted.

I. Conclusion [21 CFR 807.92(b)(3)]

The GME *TwinScan 808/755 Laser System* is substantially equivalent to the predicate devices, the *G*ME *LinScan Lite 808 System and* Asclepion *MeDioStar*; in terms of technology, function and indications for use. There are no new questions of safety or efficacy raised by the introduction of the *TwinScan 808/755 Laser System*.