July 23, 2018

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

Re: K180518
Trade/Device Name: GME LinScan Lite 808 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: June 11, 2018
Received: June 21, 2018

Dear Dr. 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. 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 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,

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

Section 4

Indications for Use

510(k) Number (if known): __NA_____

Device Name: _GME *LinScan Lite 808 Laser System*_____

Indications for Use:

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.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ (Per 21 CFR 810.109)ts

Section 5

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 07-18-2018 [21 CFR 807.92(a)(1)].

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

GME German Medical Engineering GmbH.

Grimmstrasse 23

Bavaria, Germany 90491

Tel: +49 9131 934159 0

Fax: +49 9131 934159 99

B. Contact Information

Philosopher's River llc

P O Box 106

Willow Creek, MT 59760

Tel: 406-209-3039

Fax: 406 2093039

Contact person: Mike Johnson M.D.

mike@philosophersriver.com

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

Trade Name: *LinScan Lite 808 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 *LinScan Lite 808 Laser System* uses similar technology and physical output characteristics as the following predicate device*:* K141063 GME *LinScan 808/980 System*

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

The *LinScan Lite 808 Laser System* is a diode laser designed to be used in Dermatological practice 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 *LinScan Lite 808 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 *LinScan Lite 808 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 *LinScan Lite 808 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. 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 *LinScan Lite 808 System* is compared to the predicates

- GME *LinScan 808/980 System K141063*

The indications for use and classification for the *LinScan Lite 808 System* are equivalent to the predicate. Below is a comparison table.

Characteristic	GME LinScan Lite 808 Laser System "LinScan Lite"	GME LinScan 808 and LinScan 980 "LinScan 808/980"
Applicable 510(k)s	NA	K141063
Panel/ **Product Code/ Regulation Number**	General and Plastic Surgery GEX 21 CFR 878.4810	General and Plastic Surgery GEX 21 CFR 878.4810

Indications for Use Statement	The GME LinScan Lite 808System 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 System with the applicators LinScan 808 and LinScan 980 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.
Classification	Class IV	Class IV
Common Name	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.

The specifications for the *LinScan Lite 808 System* are equivalent to the predicates. Below is a comparison table.

Characteristic	GME LinScan Lite 808 Laser System "LinScan Lite"	GME LinScan 808 and LinScan 980 "LinScan 808/980"
Applicable 510(k)s	NA	K141063
Mode of Operation	Pulsed diode laser	Pulsed diode laser
Light Source	Laser diode	Laser diode
Light Delivery	Laser and scanner are in the Applicator handpiece	Laser and scanner are in the Applicator handpiece
Cooling of Skin	Sapphire provides contact cooling.	Sapphire provides contact cooling.
Treatment Area Size	13 x 10 mm 25 x 10 mm,	15 x 10 mm, 15 x 50 mm
Peak Power	Up to 150 W	Up to 300W
Power Density	2000 W/cm^2	2000 W/cm^2

Fluence (Energy Density per Flash)	4-100 J/cm²	4-100 J/cm²
Pulse Widths	4-100 ms	4-100 ms
Repetition Rate	up to 2Hz	up to 2Hz
System Cooling	Self contained, closed water circulation system	Self contained, closed water circulation system
Wavelength	808 nm Applicator.	808 nm or 980 nm Applicator
Beam Mode	Multimode	Multimode
Aiming Beam	None	Red aiming beam laser class II
Controls	Footswitch or handswitch	Footswitch or handswitch
Electrical Requirements	100V-240V @ 50/60Hz, max. 900W	110V-240V at 50Hz, 110V-220V at 60Hz, max. 1750W
Power Calibration Method	Diode current calibrated by external power ruler	Diode current calibrated by external power ruler
Sterilization Aspects	Applicator is cleaned between patients.	Applicator is cleaned between patients.
Pulse Formation	CW current switched on / off	CW current switched on / off
Pulse Duration	4 ms – 100 ms	4 ms – 100 ms
Beam Diameter	0.75 mm x 10 mm	1 mm x 15 mm
Duty Cycle	< 100%	< 100%
Pulse Controls	Fluence, pulse duration	Fluence, pulse duration
Display	Touch Screen Control Panel	Touch Screen Control Panel

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

The GME LinScan Lite 808 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.

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 60601-2 were also submitted.

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

The GME *LinScan Lite 808 Laser System* is substantially equivalent to the predicate device, the *G*ME *LinScan 808/980 System*; in terms of technology, function and indications for use. There are no new questions of safety or efficacy raised by the introduction of the *LinScan Lite 808 Diode Laser System*.