K141063

Section 5

JUL 15 2014

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 03-08-2014 [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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C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *LinScan 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 System* uses similar technology and physical output characteristics as the following predicate devices: K090762 LEDA from Quantel Derma GmbH

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

The *LinScan* is a diode laser system designed to be used in Dermatological practice for stable, long term hair reduction.

The *LinScan System* consists of a base unit (touch screen, mains switch, key switch, Emergency Stop button), which controls an applicator unit. The applicator unit contains the diode laser and scanner. The unit comes in two models: the *LinScan 808* has an applicator with a 808 nm diode laser. The *LinScan 980* has an applicator with a 980 nm diode laser.

The *LinScan 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 System.*

Principle of Operation: The laser light is converted to heat when it strikes a chromophore (pigment). 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 *LinScan* is compared to the predicate, the Quantel Derma *LEDA*. The indications for use and intended use for the LinScan are identical to the Quantel Derma LEDA. Below is a comparison table.

Characteristic	GME *Linscan* with applicators *LinScan 808* and *LinScan 980*	Quantel Derma *LEDA* System with applicators *LEDA EPI 808* and *LEDA EPI 980*
Applicable 510(k)s	NA	K090762
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 or optional air cooling.
Treatment Area Size	15 x 10 mm or 15 x 50 mm	12 x 12 mm or 12 x 50 mm
Peak Power	Up to 300W	Up to 350 W
Fluence (Energy Density per Flash)	4-100 J/cm²	15 - 60 J/cm² (LEDA EPI 808) 15 - 90 J/cm² (LEDA EPI 980)
Pulse Widths	4-100 ms	6 – 60 ms
Repetition Rate	0.5 to 2 pulses per second depending on energy	0.5 to 1 pulse per second depending on energy.
System Cooling	Self contained, closed water circulation system	Self contained, closed water circulation system
Wavelength	808 nm (LinScan 808) 980 nm (LinScan 980)	808 nm (LEDA EPI 808) 980 nm (LEDA EPI 980)
Beam Mode	Multimode	Multimode

Beam Divergence Angel	1° Fast Axis 23.8° Slow Axis	Not known
Aiming Beam	Red aiming beam laser class II	No aiming beam
Controls	Footswitch or handswitch	Footswitch
Electrical Requirements	110 – 240 V ~ 50 Hz, 110 – 230 V ~ 60 Hz, 16 A (max. 1.75 kW)	115 – 230 V ± 10% ~ 50 Hz / 60 Hz 10 A (max. 1.1 kW)
Power Calibration Method	Diode current calibrated by external power ruler	Diode current calibrated by external power ruler
Sterilization Aspects	Applicator is disinfected between patients.	Applicator is disinfected between patients.
Pulse Formation	CW current switched on / off	CW current switched on / off
Pulse Train Duration	4 ms – 100 ms	6 ms – 60 ms
Beam Diameter	1 mm x 15 mm	1 mm x 12 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 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.

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 50) June 24, 2002 was used. Third party testing reports for IEC 60825-1 and IEC 60601-2-22 were submitted.

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

The GME *LinScan* was found to be substantially equivalent to the predicate device, the *LEDA* from Quantel Derma, in terms of technology, function and intended use. The indications for use are identical to the previously cleared device (K090762) Quantel Derma *LEDA*. We believe that there are no new questions of safety or efficacy raised by the introduction of the LinScan Diode Laser System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2014

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

Re: K141063
Trade/Device Name: GME LinScan 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 18, 2014
Received: June 26, 2014

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.

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

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)*
K141063

Device Name

GME LinScan System

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.14 12:09:29 -04'00' For BSA

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