DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

July 31, 2015

Re: K150752
Trade/Device Name: GME ExSys 308
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: June 30, 2015
Received: July 2, 2015

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,

Joshua C. Nipper -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)*
K150752

Device Name
GME ExSys 308

Indications for Use *(Describe)*
The GME ExSys 308 System is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

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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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 07-31-2015 [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 10

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: *ExSys 308 System*
Device Common Name: Ultraviolet Light for Dermatology
Classification Name: Light, Ultraviolet, Dermatological 21 CFR 878.4630
Product Code: FTC
Device Classification: Class II

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

The *ExSys 308 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 *ExSys 308* is an ultratraviolet light system designed to be used in Dermatological practice for the treatment of psoriasis and vitiligo.

The *ExSys 308 System* consists of a base unit (touch screen, mains switch, key switch, Emergency Stop button, speaker), which controls an applicator unit. The applicator unit contains the UV light source. The model number is ExSys 308.

The *ExSys 308 System* includes the following accessories: Power cord, optional foot switch, laser protective goggles, applicator holder, and set of treatment tips.

The treatment tip (a distance spacer) is the only patient contacting part of the system. There are no single use parts in the *ExSys 308 System*.

F. Principle of Operation: The UVB light penetrates the skin and modulates the immune system and stimulates melanocytes to produce melanin.

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

The *ExSys 308* is compared to the predicate, the Quantel Medical *308 Dermatological Excimer System*. The indications for use and intended use for the *ExSys 308* are identical to the Quantel Medical *308 Dermatological Excimer System*. Below is a comparison table.

Characteristic	GME ExSys 308 System "ExSys 308"	Quantel 308 Dermatological Excimer System "Quantel 308"
Applicable 510(k)s	NA	K090762
Panel/ **Product Code/ Regulation Number**	General and Plastic Surgery FTC 21 CFR 878.4630	General and Plastic Surgery FTC 21 CFR 878.4630
Indications for Use Statement	The GME ExSys 308 System is intended to be used for the treatment of psoriasis and vitiligo.	The Quantel 308 Excimer System is intended to be used for the treatment of psoriasis and vitiligo.
Mode of Operation	Continuous light source	Continuous light source
Wavelength	308 nm+/-4nm	308 nm+/-4nm
Light Source	XeCl excimer lamp produces monochromatic UVB light	XeCl excimer lamp produces monochromatic UVB light
Light Delivery	Light source is in the Applicator handpiece	Light source is in the Applicator handpiece
Cooling of Light Source	Integrated air cooling	Integrated air cooling
Treatment Area Size	50x35mm²	40x40mm²
Maximum Beam Power	875mW	800mW
Maximum Beam Power Density	50 mW/cm²	50 mW/cm^2

Beam Class	III	III
Pulse Duration	1 – 40 seconds	1-120 seconds
Applied Part Safety Class	Type B	Type B
Patient Contacting Parts	Distance Spacer made from aluminum and PMMA	Distance tips made of several materials: Quartz glass, aluminum, rubber
Controls	Footswitch or handswitch	Handswitch
Electrical Requirements	100V – 240V	100V – 240V
Power Calibration Method	Internal, automatic	Internal, automatic
Sterilization Aspects	Applicator is disinfected between patients.	Applicator is disinfected between patients.
MED Dose Determination	Menu driven	Menu driven
Duty Cycle	100%	100%
Dosage Controls	Dosage (or energy density J/cm^2), pulse duration	Dosage (or energy density J/cm^2), pulse duration
Display	Touch Screen Control Panel	Touch Screen Control Panel

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

The GME *ExSys 308 System* is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

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

Noncinical testing of performance and safety was directed by IEC 60601-2-57: Ed. 1.0, without deviation from the standard. A report of this testing was submitted. In addition, validation testing of illumination homogeneity and Treatment Tip transmission were performed. The submitted report demonstrated a less than +/- 20% deviation from illumination homogeneity and no measurable unwanted transmission around the Treatment Tip. Third party testing for EN 60601-1 and EN 60601-1-2 was performed to provide further evidence of safety.

This preclinical testing demonstrates that in terms of performance and safety, the ExSys 308 System is equivalent to the predicate device, K090762 LEDA from Quantel Derma GmbH.

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

The GME *ExSys 308* was found to be substantially equivalent to the predicate device, the *308 Dermatological Excimer System* from Quantel Medical, in terms of technology, function and intended use. The indications for use are identical to the previously cleared device (K073066) Quantel Medical *308 Dermatological Excimer System*. We believe that there are no new questions of safety or efficacy raised by the introduction of the GME *ExSys 308 System*.