March 10, 2023

GME German Medical Engineering GmbH
Dietmar Fischer
Technical Director
Dreikoenigstr. 6-8
Erlangen, Bavaria 91054
Germany

Re: K221623
Trade/Device Name: FlexSys, FlexSys UVB EPL 308 nm, FlexSys UVB EPL lite 308 nm, FlexSys IR 1550 nm
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, FTC
Dated: December 6, 2022
Received: December 12, 2022

Dear Dietmar Fischer:

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221623

Device Name
FlexSys

Indications for Use *(Describe)*
The device FlexSys is a multi-modality skin surface treatment system. Depending on the chosen modules the intended use and the mode of operation varies.

Modules UVB EPL 308 and UVB EPL 308 lite:
The GME FlexSys System with module UVB EPL 308 or UVB EPL 308 lite is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

Module Infrared 1550:
The GME FlexSys System with Infrared 1550 module is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

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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510(k) Summary
K221623

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92. Summary preparation date 2023-03-08 [21 CFR 807.92(a)(1)].

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

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Bavaria, Germany
Tel: +49 9131 934159 10
Fax: +49 9131 934159 99

B. Contact Information

GME German Medical Engineering GmbH.
Dreikoenigstrasse 6-8
91054 Erlangen
Bavaria, Germany
Contact person: Dr. Dietmar Fischer
Dietmar.fischer@gmeonline.de

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

Trade Name: *FlexSys*
Device Common Name: Laser Instrument for Dermatology
Classification Name: Laser Instrument, Surgical Powered 21 CFR 878.4810
Product Code: GEX, FTC
Device Classification: Class II

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

The *FleySys* uses similar technology and physical output characteristics as the following predicate devices*:*
K130193 Solta Medical Inc., Fraxel DUAL 1550/1927 Laser System
K150752 GME ExSys 308
K171702, K191086 Clarteis Exciplex308nm

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

The device FlexSys consists of a base unit with up to two installed internal laser modules, handpieces and/or scanners for these modules and attachable applicators. All applicators, handpieces, and scanners are connected by an electrical cable.

The base unit contains most of the controls, such as the touch-screen, the on / off switch or the emergency stop button. In addition, the power cord, foot switch, and the door plug are connected there. The touch-screen serves as the main control panel.

The applicators, handpieces, and scanners direct the light onto the skin. Some applicators contain a hand switch on the front of the handle by which light emission can be triggered.

The scanners and handpieces of the internal modules are connected to the base unit by an electric signal cable and by an optical fiber which guides the aiming beam and working beam laser light to the handpiece/scanner in its core. The light is then guided onto the skin via several mirrors and lenses. Due to the round shape of the fiber core the resulting laser spot on the skin is circular. The size of the working beam spot corresponds to the nominal value when the distance tip touches the skin. For larger distances the spot size will increase, i.e. the laser beam is divergent.

During development and manufacturing applicable directives, legal requirements and standards for medical devices were considered. Our product complies to them.

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

The device FlexSys is a multi-modality skin surface treatment system. Depending on the chosen modules the intended use and the mode of operation varies.

Modules EPL 308 and EPL 308 lite:

The GME FlexSys System with module EPL 308 or EPL 308 lite is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

Module Infrared 1550:

The GME FlexSys System with Infrared 1550 module is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

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

The FlexSys Platform is a multi-modality skin treatment device that can be equipped with up to six different modules. Thus, the predicate devices will vary from module to module. Three of these modules have already been approved, see K203054. Thus this comparison to predicates only deals with the remaining three modules, the Infrared 1550nm module and the two UVB 308nm modules.

The predicate devices used to argue substantial equivalence are the GME *ExSys 308* (K150752) and Clarteis *Exciplex* (K171702, K191086) for the UVB 308nm modules, and the Solta *Fraxel DUAL* (K130193) for the Infrared 1550nm module.

The equivalence comparisons for the UVB 308 nm wavelengths use the predicates GME *ExSys 308* and *Clarteis Exciplex*.
The equivalence comparisons for the infrared 1550 nm laser wavelength use the predicate Solta *Fraxel DUAL*.

1. UVB modules

Characteristic	GME FlexSys System Module EPL 308 "FlexSys EPL 308"	GME FlexSys System Module EPL 308 lite "FlexSys EPL 308 lite"	GME ExSys 308 "ExSys 308"	Clarteis Exciplex308nm "Exciplex"
Applicable 510(k)s	NA	NA	K150752	K171702, K191086
Panel/	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Product Code/	FTC	FTC	FTC	FTC
Regulation Number	21 CFR 878.4630	21 CFR 878.4630	21 CFR 878.4630	21 CFR 878.4630
Indications for Use Statement	The GME FlexSys System with module EPL 308 is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only	The GME FlexSys System with module EPL 308 lite is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only	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.	The Exciplex308nm is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma.
Classification	Class II	Class II	Class II	Class II
Common Name	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders
Mechanism of Action	UVB light penetrates the skin and modulates the immune system and stimulates melanocytes to produce melanin.	UVB light penetrates the skin and modulates the immune system and stimulates melanocytes to produce melanin.	UVB light penetrates the skin and modulates the immune system and stimulates melanocytes to produce melanin.	UVB light penetrates the skin and modulates the immune system and stimulates melanocytes to produce melanin.

2. Infrared 1550 module

Characteristic - -	GME FlexSys System Module Infrared 1550 "FlexSys Infrared 1550"	Solta Fraxel DUAL 1550/1927 Laser System "Fraxel"

Applicable 510(k)s	NA	K130193
Panel/	General and Plastic Surgery	General and Plastic Surgery
Product Code/	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Indications for Use Statement	The GME FlexSys System with Infrared 1550 module is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.	The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.
Classification	Class II	Class II
Common 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
Mechanism of Action	Heats water in skin through the absorption of light. The heating denatures the skin and stimulates a healing reaction by the skin.	Heats water in skin through the absorption of light. The heating denatures the skin and stimulates a healing reaction by the skin.

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 were submitted for the following standards:

- IEC 60825-1 Edition 2.0 2007-03: Safety of Laser Products – Part 1: Equipment Classification, and Requirements
- IEC 60601-2-22 Edition 3.1 2012-10: Medical Electrical Equipment – Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
- IEC 60601-1:2005, AMD1:2012: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

- IEC 60601-1-2:2014: Medical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

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

The GME *FlexSys* System is substantially equivalent to the predicate devices; in terms of technology, function and indications for use. There are no new questions of safety or efficacy raised by the introduction of the *FlexSys* System.