March 5, 2021

GME German Medical Engineering GmbH
Katja Kerl
Regulatory Affairs
Dreikoenigstrasse 6-8
Erlangen, Bavaria 91054 Germany

Re: K203054
Trade/Device Name: FlexSys
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 18, 2020
Received: October 7, 2020

Dear Katja Kerl:

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
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)*
K203054

Device Name
FlexSys

Indications for Use *(Describe)*

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

Module MultiLite:

The intended use of the device FlexSys with MultiLite module is:

• Blue 420 nm light: The GME FlexSys with Blue 420 MultiLite is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
• Yellow 585 nm light: The GME FlexSys with module Yellow 585 is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.
• Red 635 nm Light: The GME FlexSys with Red 635 MultiLite is indicated in general to treat dermatological conditions and specifically indicated to treat superficial, benign vascular, and pigmented lesions.

Module Green 532:

The GME FlexSys with module Green 532 (wavelength: 532nm) is intended for vaporization and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.

Module Yellow 577:

The GME FlexSys with module Yellow 577 (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.

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
K203054

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 01-19-2021 [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
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B. Contact Information

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Contact person:

1.) Dr. Dietmar Fischer (technical director),
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2.) Katja Kerl (regulatory affairs)
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e-mail: katja.kerl@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
Device Classification: Class II

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

The *FlexSys* uses similar technology and physical output characteristics as the following predicate devices*:*
K031425 LightBio Science L.L.C., Gentle Waves, and
K120460 Medmix Co. Ltd., SMARTLUX
K133297 Asclepion Laser Technologies GmbH, QuadroStar PRO

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 to the base unit. 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.

If you turn on the device, then the unit performs several tests automatically. Thereby the proper functioning of the device - according to the specifications - is ensured. As soon as these tests have been completed successfully, the device is ready for parameter selection and patient treatment. In addition to the initial tests a number of device functions and parameters are monitored continuously.

If the unit detects abnormalities or defects, then it reacts depending on the nature and importance by a notice, a warning or error message. This message needs to be confirmed by the user. Depending on the message one of the following cases is possible:

- the user needs to perform an action to eliminate the cause of the message (Example: The user has to take his foot off the foot switch or order a device service)
- the user must wait for a change of parameters (Example: the temperature of the device is too low, the user must wait until the unit has warmed up sufficiently.)
- the device attempts to resolve the cause of the error and performs a re-test (Example: a too high / low laser power was measured. The device performs an adjustment of power.)
- A reboot of the device is required. The device asks the user to initiate a restart.

Essential performance of the device:

- The radiation wavelength of the single modules has to lie in the range specified in the tables of section 7.1 of this user manual. This device property is tested by the manufacturer during production. No repeat measurement of this necessary.
- The light power of all laser modules has to stay within +-20% of its nominal value. This device property is check by the manufacturer during production. The light power is continuously monitored during laser emission. Laser emission will be stopped and error messages will be shown if values outside the +-20% range are detected. The calibration of the laser modules is checked by the service technician during the maintenance specified in section 6.3. The device will notify the user about necessary maintenance works. Appropriate laser power meters are used to calibrate the device in service mode according to the service instructions provided by GME.
- The applied light dose (=fluence) of all modules has to stay within +-20% of its nominal value. This device property is checked by the manufacturer during production. The applied dose is calculated from the actual light power and the emission time during light emission. In case of too high or too low dose values light emission will be stopped and the user will be notified. The calibration of the modules is checked by the service technician during the maintenance specified in section 6.3. The device will notify the user about necessary maintenance works. Appropriate laser or light power meters are used to calibrate the device in service mode according to the service instructions provided by GME.

Principle of Operation:

- For the Green 532 and Yellow 577 modules: Visible light penetrates tissue up to a depth of about 1 mm. When the laser radiation hits the skin, the light is mainly absorbed by melanin and hemoglobin in the skin. Melanin and hemoglobin-containing structures such as pigment spots or blood vessels heat up more strongly than the surrounding skin. This causes irreversible damage or coagulation of the structures.
- For the MultiLite module: Visible light penetrates tissue up to a depth of about 10 mm. Light at this wavelength is beneficial in treating bengin dermatological lesions. LED photo modulation with visible light reverses signs of aging using a nonthermal mechanism.
  Blue, LED therapy can destroy the bacteria associated with acne lesions because the light generates oxygen radicals in very active cells (like bacteria or cancer cells) which destroy the cell walls and thus lead to necrosis or apostosis of the cells.

F. 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 three different modules. Thus the predicate devices will vary from module to module.

The predicate devices used to demonstrate substantial equivalence are the the Asclepion *QuadroStar Pro* (K133297), the Medmix *Smartlux* (K120460), and the Light Bioscience *GentleWaves* (K031425).

The equivalence comparisons for the visible 532 nm and 577 nm laser wavelengths use the predicate Asclepion *QuadroStar Pro* (K133297).
The equivalence comparisons for the visible LED module Multilite use the predicates Medmix *Smartlux* (K120460) and Light Bioscience *GentleWaves* (K003142).

1. Green 532 and Yellow 577 module

Characteristic	GME FlexSys Module Green 532 "FlexSys Green 532"	GME FlexSys Module Yellow 577 "FlexSys Yellow 577"	Asclepion QuadroStarPRO "QuadroStar"
Applicable 510(k)s	NA	NA	K133297
Panel/	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Product Code/	GEX	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Indications for Use Statement	NA	The GME FlexSys with module Yellow 577 (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.	The QuadroStarPRO YELLOW (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.
	The GME FlexSys with module Green 532 (wavelength: 532nm) is intended for vaporization and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.	NA	The QuadroStarPRO GREEN (wavelength: 532nm) is intended for vaporisation and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.
Classification	Class II	Class II	Class II
Common Name	Diode-pumped solid state laser	Diode-pumped solid state laser	Diode-pumped solid state laser
Mechanism of Action	Heats chromophores (vessels or pigments) and water in the skin through the absorption of light. The heating denatures the target structures.	Heats chromophores (vessels or pigments) and water in the skin through the absorption of light. The heating denatures the target structures.	Heats chromophores (vessels or pigments) and water in the skin through the absorption of light. The heating denatures the target structures.

2. MultiLite module

Characteristic	GME FlexSys Module MultiLite "FlexSys MutiLite"	Medmix Smartlux "Smartlux"	Light Bioscience GentleWaves LED Photomodulation Device "GentleWaves"
Applicable 510(k)s	NA	K120460	K031425
Panel/	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery

Product Code/	GEX	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Indications for Use Statement - -	Blue: Dermatological conditions and specifically treatment of moderate inflammatory acne vulgaris Yellow: Treatment of periorbital wrinkles and rhytides Red: Treatment of superficial, benign vascular, and pigmented lesions	415nm wavelength: Derrnatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris 633nm wavelength: Dermatology for treatment of superficial, benign vascular, and pigmented lesions	NA 588nm wavelength: The GentleWaves LED Photomodulation Device is indicated/intended for use in the treatment of periorbital wrinkles and rhytides NA
Classification	Class II	Class II	Class II
Common Name	LED light source	LED light source	LED light source
Mechanism of Action	Reduces inflammation and stimulates collagen production via photomodulation effect of the light penetrating the skin.	Reduces inflammation and stimulates collagen production via photomodulation effect of the light penetrating the skin.	Stimulates collagen production via photomodulation effect of the light penetrating the skin.

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

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

Module MultiLite:

The intended use of the device FlexSys with MultiLite module is:

- Blue 420 nm light: The GME *FlexSys* with Blue 420 *MultiLite* is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
- Yellow 585 nm light: The GME *FlexSys* with module Yellow 585 is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.
- Red 635 nm Light: The GME FlexSys with Red 635 *MultiLite* is indicated in general to treat dermatological conditions and specifically indicated to treat superficial, benign vascular, and pigmented lesions.

Module Green 532:

The GME *FlexSys* with module Green 532 (wavelength: 532nm) is intended for vaporization and photocoagulation of benign vascular and benign pigmented lesions in soft tissue.

Module Yellow 577:

The GME *FlexSys* with module Yellow 577 (wavelength: 577nm) is intended for treatment of benign vascular and benign pigmented lesions.

H. Discussion of nonclinical tests [21 CFR 807.92(b)(1)]

The Guidance Document, Laser Products – Conformance with EN 60825-1:2015-07 and EN 60601-2-22: 2015-08 (Laser Notice 56: 2018-05-08) was used.
Testing reports for EN 60825-1:2015-07 and EN 60601-2-22:2015-08 were submitted.
Testing reports for EN 60601-1:2013-12 and EN 60601-1-2:2016-05 were also submitted. The European version of the standards (EN) have been used for the tests, but they are identical in all test requirements to the IEC versions of the standards.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Sofware documentation provided is consistent with a moderate level of concern.

Biocompatibility:The body-contacting component for the FlexSys uses identical stainless-steel material as in FDA cleared reference devices Wavelight IDAS (K053604) and Wavelight ARION (K042474). Therefore, biocompatibility testing is not required.

Usability was established based on standards EN 62366-1:2015 + AC:2015 and EN 60601-1-6:2010+A1:2015

Shelf life was established to be 10 years.

Clinical Performance Data: None

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

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of technology, function, indications for use, design, materials and performance, The GME *FlexSys* is to be concluded substantially equivalent to the predicate devices. There are no new questions of safety or efficacy raised by the introduction of the *FlexSys*.