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

December 8, 2016

Bios S.R.L.
Manuela Brambilla
Regulatory and Quality Assistant
Via Guido Rossa, 10/12
Vimodrone, Milan I-20090 IT

Re: K161632
Trade/Device Name: Family Of Square Epil (Alex, Alex2, Nd:YAG, Alex+Nd:YAG)
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: November 2, 2016
Received: November 14, 2016

Dear Manuela Brambilla:

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" (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 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,

Jennifer R. Stevenson -A

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)*
K161632

Device Name
FAMILY OF SQUARE EPIL (Square Epil Alex, Square Epil Alex2, Square Epil Nd:Yag, Square Epil Alex+Nd:Yag)

Indications for Use *(Describe)*
The Nd:Yag 1064 Laser is intended for:
- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.
The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of benign pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.
- Coagulation and hemostasis of soft tissue.
- Treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafè au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.
The laser is indicated for benign pigmented lesions to reduce lesion size, for patients with benign lesions that would potentially benefit from aggressive treatment, and for patients with benign lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of wrinkles.
The Nd:Yag 1064 Laser is intended for:
- Temporary increase of clear nail in patients with onychomycosis (e.g., derniatophytes, Trichophyton rubrum and T. mentagrophytes, and for yeast Candida Albicans, etc.)

The Alexandrite 755 laser is intended for:
- Temporary hair reduction.
- Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I – VI) including tanned skin.
- Treatment of benign pigmented lesions.
- Treatment of wrinkles.
- Photocoagulation of dermatological benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

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

I. SUBMITTER

Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20090 Vimodrone (MI) – Italy
Contact	Ing. Aldo Casalino
Date Prepared	7 June 2016

II. DEVICE

Device Trade Name	FAMILY OF SQUARE EPIL (Square Epil Alex, Square Epil Alex2, Square Epil Nd:Yag, Square Epil Alex+Nd:Yag)
Common Name	Medical Laser System
Regulatory class	II
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product Code	GEX

III. PREDICATE DEVICE

510(k) Number	Pro Code	Trade Name	Applicant
K150516	GEX 21 CFR 878.4810	DEKA Synchro	El. En. Electronic Engineering S.p.A.
K140122	GEX 21 CFR 878.4810	Candela Corporation	GentleMAX Family of Laser Systems

IV. Device Description

The FAMILY OF SQUARE EPIL LASER , is a laser equipped with one or two solid-state laser sources: As shown in the previous table, the 4 configurations of the Family differ for the internal crystals of the sources, that can be Alexandrite and/or Nd:YAG. The emitted laser radiation has a wavelength of 755nm, respectively, and 1064nm:

-Alex configuration has only one source and one wavelength available (755 nm).

-Alex^2 configuration has two sources of the same wavelength (755 nm), in order to increase the maximum power available.

-Nd:Yag configuration has only one source and one wavelength available (1064 nm).

-In the Alex+Nd:Yag configuration has both the two wavelengths available (755 nm and 1064 nm) but can act only individually, simultaneous operations are not allowed.

This device is intended for medical use only.

V. Indication for Use

The Nd:Yag 1064 Laser is intended for:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of benign pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.

Coagulation and hemostasis of soft tissue.

Treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafè au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for benign pigmented lesions to reduce lesion size, for patients with benign lesions that would potentially benefit from aggressive treatment, and for patients with benign lesions that have not responded to other laser treatments.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

The Nd:Yag 1064 laser is intended for:

Temporary increase of clear nail in patients with onychomycosis (e.g., derniatophytes, Trichophyton rubrum and T. mentagrophytes, and for yeast Candida Albicans, etc.).

The Alexandrite 755 laser is intended for:

Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

The photocoagulation of dermatological benign vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias)

VI. Comparison of Technological Characteristics with the Predicate Devices

The product specification, functionality, indication for use, and treatment parameters of the FAMILY OF SQUARE EPIL LASER are the same or very similar to the legally marketed, claimed predicate devices for the purpose of this 510(k) submission.

The general features of FAMILY OF SQUARE EPIL LASER are similar to those of the predicates in particular as regards the classification IV laser and the electrical specifications. Also the predicate devices are equipped with a touch screen and with a control SW. The physical characteristics of FAMILY OF SQUARE EPIL LASER (weight and size) are also comparable with those of the predicates.

The intended use of each configuration of FAMILY OF SQUARE EPIL LASER are identical to those of the predicates and also the technical characteristics are the same.

In particular:

- Nd:Yag source of FAMILY OF SQUARE EPIL LASER with the wavelength of 1064 nm applies a maximum energy in the same range of DEKA Synchro K150516 and the GentleMAX Family of Laser Systems K140122.

  The emission frequency of the Nd:Yag source of FAMILY OF SQUARE EPIL LASER is the same of DEKA Synchro K150516 and the GentleMAX Family of Laser Systems K140122.

- Nd:Yag Source of FAMILY OF SQUARE EPIL LASER with the wavelength of 1064 nm, are shown operative parameters for a specific application (Temporary increase of clear nail in patients with onychomycosis). These parameters are identical to the predicate device GentleMAX Family of Laser Systems K140122.
- Alexandrite source of FAMILY OF SQUARE EPIL LASER with the wavelength of 755 nm applies a maximum energy in the same range of DEKA Synchro K150516 and the GentleMAX Family of Laser Systems K140122.

  The emission frequency of the Alexandrite source of FAMILY OF SQUARE EPIL LASER are comparable to DEKA Synchro K150516 and the GentleMAX Family of Laser Systems K140122.

VII. Performance Data

Biocompatibility testing

The FAMILY OF SQUARE EPIL LASER is classified as a surface device (≤ 24 hours contact duration) in contact with skin in accordance with ISO 10993.

The patient contacting materials for the device and accessories are all well known for their compatibility.

Electrical safety and EMC

The FAMILY OF SQUARE EPIL LASER has been tested and is in compliance with:

- EN 60601-1, Medical electrical equipment. Part 1: General requirements for basic safety and essential performance 2006/A11:2010/A1:2013, EN 60601-2-22:2013 Medical electrical equipment;
- EN60601-1-2 Medical electrical equipment. Part1: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests.

Software verification and validation testing

Software verification and validation was conducted according to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed on the FAMILY OF SQUARE EPIL LASER in compliance with internal design control procedures.

Usability testing

Usability of the FAMILY OF SQUARE EPIL LASER have been tested in accordance with the standard EN 60601-1-6:2010

Pre series test

Pre-series tests have been performed to support the evidence that performances of FAMILY OF SQUARE EPIL LASER are aligned with the identified intended uses.

Animal and clinical study

Animal and clinical studies were not necessary to demonstrate that the permormances are comparable to the predicate devices.

VIII. Conclusions

BIOS s.r.l. has determined, by using comparisons and tests, that FAMILY OF SQUARE EPIL LASER is substantially equivalent to the listed predicate devices in terms of intended use, typical clinical use, operational characteristics, and fundamental technological characteristics. Any differences are considered minor and do not raise new issues of the safety and effectiveness of the FAMILY OF SQUARE EPIL LASER device when compared to the predicate devices.