



Food and Drug Administration
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April 12, 2016

Bios S.r.l
Mr. Riccardo Pisati
Regulatory Affairs
Via Guido Rossa, 10/12
Vimodrone, IT-20090 Milan

Re: K153229

Trade/Device Name: Superbium
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, ONG, ONF
Dated: March 21, 2016
Received: March 25, 2016

Dear Mr. Pisati:

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 yours,

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

Indications for Use

510(k) Number (if known)
K153229

Device Name
Superbium

Indications for Use (Describe)

The Nd:Yag 1064 Laser Handpiece (Long Pulsed) is intended for:

- treatment of benign vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins;
- treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratoses, nevi, chloasma, cafe-au-lait macules, and plaques;
- tattoos (significant reduction in the intensity of black and/or blue-black tattoos); verrucae, skin tags, seborrheic keratosis;
- reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;
- coagulation and hemostasis of soft tissue;
- the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction. Permanent reduction in hair regrowth 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 Nd:Yag 1064 Laser Handpiece (Short Pulsed) is intended for:

Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions
Laser skin treatment procedures for the treatment of: Acne scars, Wrinkles

The Nd:YAG Q-Switched Handpieces (1064 nm) are indicated for treatment of:

- Benign vascular lesions such as, but not limited to treatment of:
Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas
- Benign cutaneous lesions, such as, but not limited to:
Warts; Scars; Striae; Psoriasis
- Benign pigmented lesions such as, but not limited to:
Lentigos (age spots); Solar lentigos (sun spots); Cafe-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; Verrucae; Skin tags; Keratoses; The removal of black, blue or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos); Plaques
- Pigmented benign lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
Periocular wrinkles; Perioral wrinkles;
- Laser skin resurfacing procedures for the treatment of:
Acne scars; Wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Nd:YAG Q-Switched Handpieces (532 nm) are indicated for treatment of:

- Incision, excision, ablation, vaporization of soft tissue.
- Tattoo removal: Light blue; Yellow; Red; Green
- Vascular lesions: Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); Angiomas (cherry, spider); Telangiectasia; Spider nevi
- Benign pigmented lesions: Cafe-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus; Nevus of Ota; Becker's Nevi

The 2940 nm Er:YAG Laser Module handpiece is indicated for:

Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

Laser skin resurfacing procedures for the treatment of:

- Acne scars
- Wrinkles

The 2940 nm Er:Yag Fractional tips are indicated for:

Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to:

Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic cheilitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

The 1540 Fractional Non-ablative Laser Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

IPL 400-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of benign cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

IPL500-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne (acne vulgaris).
- The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on Fitzpatrick skin types I-V.

IPL 550-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne Vulgans.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body vascular and pigmented lesions.
- The treatment of cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI).

IPL 580-1200 run handpiece is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body vascular and pigmented lesions.
- The treatment of cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI).

IPL 620-1200 nm handpiece is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait.
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- : The removal of unwanted hair and to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

IPL 755-1200 nm handpiece is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis.
- The treatment of pseudofolliculitis barbae (PFB).
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

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)

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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 3 November 2015

II. DEVICE

Device Trade Name SUPERBIUM

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, ONG, ONF

III. PREDICATE DEVICE

510(k) Number	Pro Code	Trade Name	Applicant
K072344	GEX 21 CFR 878.4810 FTC 21 CFR 878.4630	APL MEDICAL SYSTEM	BIOS
K103664	GEX, ONG 21 CFR § 878.4810	ICON AESTHETIC SYSTEM	Palomar
K072564	GEX, FTC, HHR, LNK 21 CFR 878.4810	HARMONY XL MULTI APPLICATION PLATFORM	ALMA
K150140	GEX 21 CFR 878.4810	DERMABLATE	ASCLEPION
K111303	GEX 21 CFR 878.4810	OMNIMAX	SHARPLIGHT TECHNOLOGIES
K090195	GEX 21 CFR 878.4810	LUX 1540	PALOMAR

IV. DEVICE DESCRIPTION

The portable device SUPERBIUM, is a multilaser and pulsed light system, designated to act on some common conditions of face and body (as specified in detail in Section 4). The equipment is designed as an expandable system for dermatologic and general surgery procedures, composed of a modular platform, which contains the entire electronics of the system and the cooling circuit, and a series of interchangeable

handpieces to be connected on the platform, intended to treat specific groups of imperfections. A quick connection enables the quick and easy replacement of the various hand pieces that can be mounted on the modular platform. The following handpieces are available:

- 1) Handpiece Nd:Yag Laser contains a flash lamp excited source that emits at 1064nm, with 2 different modalities: long pulse (ms) and short pulse (μ s). The handpiece can be equipped with different spots and also with an optical fiber. A pointing laser helps to guide the operator during the treatment. With this laser it is possible to treat vascular lesions, pigmented lesions, tattoos, scars, soft tissue, hair removal treatments (long pulse) and pigmented and vascular lesions, wrinkles and podiatry (short pulse). This laser is class IV according to the Standard EN60825-1.
- 2) Handpiece Nd:Yag Laser contains a flash lamp excited source that emits 1064 and 532 nm Qs (Q-Switched). The pulse duration is very short (ns), typical characteristic of QS lasers. The handpiece can be equipped with different spots. A pointing laser helps to guide the operator during the treatment. The Qs laser is ideal for the treatment of vascular lesions, scars, pigmented lesions, skin resurfacing (1064 nm) and soft tissue, tattoo, vascular lesions, pigmented lesions (532 nm). This laser is class IV according to the Standard EN60825-1.
- 3) Handpiece Erbium Laser contains a flash lamp excited source that emits at 2940 nm. The handpiece can be equipped with different spots; two of them are fractional, so they divide the shot in several microbeams. The Er:Yag laser is ideal for soft tissue, skin resurfacing, skin lesions treatments. This laser is class IV according to the Standard EN60825-1.
- 4) Handpiece Erbium Glass Laser contains a flash lamp excited source that emits at 1540 nm. The handpiece can be equipped with two spots, both fractional, that divide the shot in several microbeams. The Er:Glass is ideal for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue, for example scar treatments. This laser is class IV according to the Standard EN60825-1.
- 5) Handpiece Pulsed Light contains a xenon lamp that emits from 400 and 1200 nm. On this handpiece it is possible to change easily the guide light, equipped with a specific light filter and to use thus that one most adequate for the individual photo type. It is possible also to have a cooling for the guides, as optional. With the use of this handpiece is possible to perform pigmented lesions, scars, vascular lesions, tattoos, hair removal.

V. Indication for Use

The Nd:Yag 1064 Laser Handpiece (Long Pulsed) is intended for:

- treatment of vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins;
- treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratoses, nevi, chloasma, café-au-lait macules, and plaques;
- tattoos (significant reduction in the intensity of black and/or blue-black tattoos); verrucae, skin tags, seborrheic keratosis;
- reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;
- coagulation and hemostasis of soft tissue;
- the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction. Permanent reduction in hair regrowth 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 Nd:Yag 1064 Laser Handpiece (Short Pulsed) is intended for:

Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions
Laser skin treatment procedures for the treatment of: Acne scars, Wrinkles

The Nd:YAG Q-Switched Handpieces (1064 nm) are indicated for treatment of:

- Benign vascular lesions such as, but not limited to treatment of:
Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas
- Benign cutaneous lesions, such as, but not limited to:
Warts; Scars; Striae; Psoriasis
- Benign pigmented lesions such as, but not limited to:
Lentigos (age spots); Solar lentigos (sun spots); Café-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; Verrucae; Skin tags; Keratoses; The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos); Plaques
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
Periocular wrinkles; Perioral wrinkles;
- Laser skin resurfacing procedures for the treatment of:
Acne scars; Wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Nd:YAG Q-Switched Handpieces (532 nm) are indicated for treatment of:

- Incision, excision, ablation, vaporization of soft tissue.
- Tattoo removal: Light blue; Yellow; Red; Green
- Vascular lesions: Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); Angiomas (cherry, spider); Telangiectasia; Spider nevi

- Benign pigmented lesions: Café-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spilius; Nevus of Ota ;Becker's Nevi
- Other pigmented cutaneous lesions: Verrucae; Skin tags; Keratoses; Plaques

The 2940 nm Er:YAG Laser Module handpiece is indicated for:

Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

Laser skin resurfacing procedures for the treatment of:

- Acne scars
- Wrinkles

The 2940 nm Er:Yag Fractional tips are indicated for:

Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to:

Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).

The 1540 Fractional Non-ablative Laser Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

IPL 400-1200 run handpiece is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

IPL500-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne (acne vulgaris).
- The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on Fitzpatrick skin types I-V.

IPL 550-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body vascular and pigmented lesions.
- The treatment of cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI).

IPL 580-1200 nm handpiece is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body vascular and pigmented lesions.
- The treatment of cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI).

IPL 620-1200 nm handpiece is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait.
- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

IPL 755-1200 nm handpiece is indicated for:

- The treatment of tattoos.
- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).

- The treatment of cutaneous lesions including warts, scars and striae.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis.
- The treatment of pseudofolliculitis barbae (PFB).
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

By comparing SUPERBIUM to the legally marketed predicate devices, it is substantially equivalent in terms of intended use and utilizes similar functional features including energy source, frequency, fluency, pulse width.

The general features of SUPERBIUM are similar to those of the predicates in particular as regards the classification IV laser, the equipment of a the cooling system and the electrical specifications. Also the predicate devices are equipped with a touch screen and with a control SW.

The intended use of each handpiece of SUPERBIUM are identical to those of the handpieces of the predicates and also the technical characteristics are the same, in particular:

- handpiece Nd:Yag Long Pulse of SUPERBIUM with the wavelength of 1064 nm applies an output power and a maximum energy per pulse operating in the same range of Harmony XL K072564 and the Icon Aesthetic System K103664.

The emission frequency of the handpiece Nd:Yag Long Pulse of SUPERBIUM is the same of Harmony XL K072564 and it is in the same interval the Icon Aesthetic System K103664.

- handpiece Nd:Yag Short Pulse of SUPERBIUM with the wavelength of 1064 nm applies an output power and a maximum energy per pulse operating, in the same range of APL Medical System K072344.
- handpiece Nd:YAG Q-Switched of SUPERBIUM with a wavelength of 1064+532 nm applies a maximum output power and a maximum energy per pulse similar to those of the Harmony XL K072564. The pulse duration is in the same range of predicates and fluence value is similar to that of the Harmony XL K072564. The emission frequency of the handpiece Nd: YAG Q-Switched of SUPERBIUM is the same of predicates.
- handpiece Er:Yag of SUPERBIUM with a wavelength of 2940 nm applies a maximum output power in the same range of values APL Medical System K072344 and of the Dermablade K150140 and a maximum energy per pulse that is the same value of Dermablade K150140. The value of the fluence the same to predicate devices Dermablade K150140 for the same spot size. The emission frequency of the handpiece Er:Yag of SUPERBIUM is similar to that of the Dermablade K150140.

- handpiece Er:Yag Fractional Tip of SUPERBIUM is equal to the predicate SHARPLIGHT TECHNOLOGIES OMNIMAX K1113603. The numbers of dots are the same, and also the fluencies are very similar. The frequency emission is the same.
- handpiece Er:Yag Glass of SUPERBIUM with a wavelength of 1540 nm is equal to the predicate Palomar LUX 540 K090195. In particular they have same parameters for max energy, dot density and consequently the fluence parameters are the same. Also the pulse duration and the emission frequency are equal to the predicate.
- the IPL handpiece of SUPERBIUM has the same emission spectrum (400 - 1200 nm) of the Harmony XL K072564 and of APL Medical System K072344. The standard filters equipment is the same and also the maximum energy per pulse is in the same range of mentioned predicates. The maximum fluence value is the same and the values of the maximum pulse duration and frequency are similar.

A) General Features

Device Basic Technical Data	Applicant	BIOS	BIOS	Palomar	ALMA	ASCLEPION	SHARPLIGHT TECHNOLOGIES	PALOMAR
	Device Name	SUPERBIUM	APL MEDICAL SYSTEM	ICON AESTHETIC SYSTEM	HARMONY XL	DERMABLATE	OMNIMAX	LUX 1540 Handpiece
	510k	---	K072344	K103664	K072564	K150140	K111303	K090195
	Classification	GEX 21 CFR 878.4810, ONF 21CFR 878.4810	GEX 21 CFR 878.4810 FTC 21 CFR 878.4630	GEX, ONG 21 CFR § 878.4810	GEX, FTC, HHR, LNK 21 CFR 878.4810	GEX 878.4810	GEX 878.4810	GEX 878.4810
Intended Use	Nd:Yag Handpiece LP		See Table B	See Table B	See Table B	-	-	-
	Nd:Yag Handpiece SP		See Table C	-	-	-	-	-
	Nd:Yag Q-Switched Handpiece		See Table D	-	See Table D	-	-	-
	Er:Yag Handpiece		See Table E	-	-	See Table E	-	-
	Er:Yag Handpiece Fractional		-	-	-	-	See Table F	-
	Er:Yag Glass Handpiece		-	-	-	-	-	See Table G
	IPL Handpiece		See Table H	-	See Table H	-	-	-
Display	Display LCD 10.4" touch screen.		LCD Color Display "touch screen".	LCD Color Display "touch screen".	LCD Color display "touch screen"	Display "touch screen"	Display "touch screen"	-
Voltage	110V Ac ±10%		110V Ac ±10%	90 - 264 VAC	100 -120 VAC	110V Ac	100-240 V	
Frequency	60 Hz ± 1%		60 Hz ± 1%	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz	50-60Hz,	
Absorbed power	12A (average)– 24A max		8A (average)– 12,5A max	20 A	20 A	500 VA	max 1-A	-
Cooling system	YES		YES	YES	YES	YES	YES	-
Laser class	IV		IV	IV	IV	IV	IV	IV
Weight	35 Kg		Approx 21 Kg	47.17 Kg	Upper Unit 15 kg, Lower Unit 45 kg	75 Kg	70kg	-
Dimensions (LxPxH) cm	Base: 50x54x38		50x45x25 cm	58x54x103 cm	39.7 x 55 x 123 cm	36 x 60 x 93 cm	56 x 42 x 105 cm	-

B)Nd:Yag Handpiece Long Pulse

Applicant	BIOS	BIOS	ALMA	PALOMAR
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL	ICON AESTHETIC SYSTEM
510k	---	K072344	K072564	K103664
Classification	GEX 21 CFR 878.4810, ONF	GEX, FTC	GEX, FTC, HHR, LNK	GEX, ONG
Laser source	Nd:YAG LP	Nd:YAG LP	Nd:Yag LP	Nd:Yag
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm
Output power	45W max	20W max	40W max	50 W
Max energy per pulse	LP: 45J (max)	LP: 20J (max)	40 J	50 J
Beam diameter (spot)	1, 2, 3, 4, 5, 6, 9, 11,12,13,14,15 mm	2; 5 mm	6 mm	1,5; 3; 6; 10 mm
Fluence	500J/cm2 (max); 3 mm: 500J/cm2 (max); 6 mm: 160 J/cm2	285 J/cm2 (spot 3mm)	30-450 J/cm2 (2); 30-150 J/cm2 (6); 30-450 J/cm2 (10)	1,5 mm - 250/750 J/cm2; 3 mm - 70/450 J/cm2; 6 mm - 16/140 J/cm2; 10 mm - 7/50 J/cm2
Pulse duration	LP: 1 - 25 ms	LP: 5 - 25 ms	8-15ms (2); 40-60 ms (6); 15 ms (10)	10 - 100 ms
Emission frequency	LP: 1 Hz (max)	LP: 1 Hz (max)	1 Hz	0,2 - 2 Hz
Intended Use	The Nd:Yag 1064 Laser Handpiece (Long Pulsed) is intended for:		1064 nm Long Pulsed Module Handpieces The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of:	The 1064 Laser Handpiece is intended for
	- treatment of vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins;	6. treatment of capillaries, telangiectasias and vascular lesions (LP)	• Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas	treatment of vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins;

Applicant	BIOS	BIOS	ALMA	PALOMAR
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL	ICON AESTHETIC SYSTEM
510k	---	K072344	K072564	K103664
	- treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratoses, nevi, chloasma, cafe-au-lait macules, and plaques;		<ul style="list-style-type: none"> • <i>Benign cutaneous lesions, such as, but not limited to:</i> Warts; Scars; Striae; Psoriasis 	treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratoses, nevi, chloasma, cafe-au-lait macules, and plaques;
	- tattoos (significant reduction in the intensity of black and/or blue-black tattoos); verrucae, skin tags, seborrheic keratosis;		<ul style="list-style-type: none"> • <i>Benign pigmented lesions such as, but not limited to:</i> Lentigos (age spots); Solar lentigos (sun spots); Café-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; Verrucae; Skin tags; Keratoses; The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos); Plaques 	tattoos (significant reduction in the intensity of black and/or blue-black tattoos); verrucae, skin tags, seborrheic keratosis;
	- reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;		Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles	reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;
	- coagulation and hemostasis of soft tissue;		Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.	coagulation and hemostasis of soft tissue;

Applicant	BIOS	BIOS	ALMA	PALOMAR
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL	ICON AESTHETIC SYSTEM
510k	---	K072344	K072564	K103664
	<ul style="list-style-type: none"> - the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction; 	1. The removal of unwanted hair and to effect stable long-term or permanent hair reduction (LP)	1064 nm Long Pulsed Only Nd:YAG Laser Module Handpieces The 1064 nm Nd:YAG lasers (Long Pulsed only, with and without contact-cooling) is indicated for: <ul style="list-style-type: none"> - Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. - Removal or lightening of unwanted hair (with and without adjuvant preparation) - Treatment of pseudofolliculitis barbae (PFB) - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned 	the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction

C)Nd:Yag Handpiece - Short Pulse

Applicant	BIOS	BIOS
Device Name	SUPERBIUM	APL MEDICAL SYSTEM
510k	---	K072344
Classification	GEX 21 CFR 878.4810, ONF	GEX, FTC
Laser source	Nd:YAG SP	Nd:YAG SP
Wavelength	1064 nm	1064 nm
Output power	45W max	20W max
Max energy per pulse	1000 mJ	2000 J (max)
Beam diameter (spot)	6, 9	2/5 mm
Fluence	6 mm: 3.6 J/cm ² 9 mm: 1.6 J/cm ²	spot 5 mm: 10 J/cm ²
Pulse duration	SP: 200 – 700 µs	SP: 100 – 500 µs
Emission frequency	SP: 10Hz (max)	SP: 3 Hz (max)
Intended Use	Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions (SP) Laser skin treatment procedures for the treatment of: Acne scars, Wrinkles (SP)	5. removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions (SP) 2. Laser skin treatment procedures for the treatment of: Acne scars, Wrinkles (SP)

D)Nd:Yag Q-Switched Handpiece

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX, FTC	GEX, FTC, HHR, LNK
Laser source	Nd:YAG Q - Switched	Nd:YAG – Q Switched	Nd:YAG – Q Switched
Wavelength	1064+532 nm.	1064+532 nm.	1064+532 nm.
Output power	10W max	1,2 W max	0,4 - 6 W
Max energy per pulse	1800 mJ (max).	1000 mJ	400- 1200 mJ
Pulse duration	up to 12 ns	10 ns	20 ns
Fluence	180 J/cm2	32 J/cm2 (spot 2 mm)	152 J/cm2 max
Emission frequency (max)	5 Hz	5 Hz	1; 2; 5 Hz
Beam diameter (spot)	2, 4, 10 mm; 1-2-3-3,5 mm	1; 3 mm	1; 2; 3;4; 5; 6 mm
Intended Use	<p>The Nd:YAG Q-Switched Handpieces (1064 nm) are indicated for treatment of:</p> <p>- Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas</p> <p>- Benign cutaneous lesions, such as, but not limited to: Warts; Scars; Striae; Psoriasis</p> <p>- Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Cafè-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; Verrucae; Skin tags; Keratoses; The removal of</p>		<p>1064 nm Long Pulsed and Q-Switched Nd:YAG Laser Module Handpieces</p> <p>The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of.</p> <p>• Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas</p> <p>• Benign cutaneous lesions, such as, but not limited to: Warts; Scars; Striae; Psoriasis</p> <p>• Benign pigmented lesions such as, but not limited to:</p>

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos); Plaques</p> <ul style="list-style-type: none"> - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles; Perioral wrinkles; - Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. 		<p>Lentigos (age spots); Solar lentigos (sun spots); Café-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; Verrucae; Skin tags; Keratoses; The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos); Plaques</p> <ul style="list-style-type: none"> • Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. • The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles; Perioral wrinkles; • Laser skin resurfacing procedures for the treatment of: Acne scars; Wrinkles • Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. • Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
	<p>The Nd:YAG Q-Switched Handpieces (532 nm) are indicated for treatment of:</p> <ul style="list-style-type: none"> - Incision, excision, ablation, vaporization of soft tissue. - Tattoo removal: Light blue; Yellow; Red; Green - Vascular lesions: Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); Angiomas (cherry, spider); Telangiectasia; Spider nevi - Benign pigmented lesions: Café-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus; Nevus of Ota ;Becker's Nevi - Other pigmented cutaneous lesions: Verrucae; Skin tags; Keratoses; Plaques 	<p>5. removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions</p>	<p>532 nm Long Pulsed and Q-Switched FD Nd:YAG Laser Module Handpiece Tips The 532 nm Frequency-Doubled (FD) Nd:YAG Laser Module handpieces tips (Long Pulsed and Q-Switched, with and without contact-cooling) are indicated for:</p> <ul style="list-style-type: none"> • Incision, excision, ablation, vaporization of soft tissue. • Tattoo removal: Light blue; Yellow; Red; Green • Vascular lesions: Hemangiomas (Port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); Angiomas (cherry, spider); Telangiectasia; Spider nevi • Benign pigmented lesions: Café-au-lait (macules); Lentigines (senile and solar); Freckles (ephelides); Chloasma; Nevi; Nevus spillus; Nevus of Ota ;Becker's Nevi • Other pigmented cutaneous lesions: Verrucae; Skin tags; Keratoses; Plaques

E) Er:Yag Handpiece

Applicant	BIOS	BIOS	Asclepion
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	DERMABLATE
510k	---	K072344	K150140
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX, FTC	GEX
Laser source	Er:YAG	Er:YAG	Er:YAG
Wavelength	2.940 nm.	2.940 nm.	2.940 nm.
Output power	12 W max	4 W	20 W
Max energy per pulse	2,5 J (max).	800 mJ (max)	2,5 mJ
Beam diameter (spot)	1/ 9 mm	2 -8 mm	1/12 mm
Fluence	316 J/cm ² (spot 1 mm)	22 J/cm ² (spot 2 mm)	318 J/cm ² (spot 1 mm)
Emission frequency	5 Hz	5 Hz	20 Hz
Intended Use	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes). Laser skin resurfacing procedures for the treatment of: <ul style="list-style-type: none"> · Acne scars · Wrinkles 	Laser skin resurfacing procedures for the treatment of: <ul style="list-style-type: none"> · Acne scars · Wrinkles Incision, excision, ablation, vaporization of soft tissue.	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

F) Er:Yag Handpiece Fractional Tip

Applicant	BIOS	SHARPLIGHT TECHNOLOGIES
Device Name	SUPERBIUM	OMNIMAX
510k	K153229	K111303
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX NUV, ONG, ONE, ONF
Laser source	Er:YAG	Er:YAG
Wavelength	2.940 nm	2.940 nm
Beam diameter (dots)	7x7 9x9	7x7 9x9
Fluence	25 mJ/dot (7x7 mm) 13 mJ/dot (9x9 mm)	25 mJ/dot (7x7 mm) 13 mJ/dot (9x9 mm)
Emission frequency	Up to 1,5 Hz	Up to 1,5 Hz
Intended Use	<p>The Er:Yag Fractional tips are indicated for: Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: *Dermatology and plastic Surgery: Skin resurfacing3 Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).</p>	<p>Use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: *Dermatology and plastic Surgery: Skin resurfacing3 Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars);</p>

G)Er:Yag Glass Handpiece

Applicant	BIOS	PALOMAR
Device Name	SUPERBIUM	LUX 1540
510k	K153229	K090195
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX
Laser source	Er:Glass	Er:Glass
Wavelength	1540 nm	1540 nm
Max energy per pulse	10 J	10 J
Dot Density (Dot/cm ²)	100; 320	100; 320
Fluence	100mJ/dot (max) (100 dots) 31mJ/dot (max) (320 dots)	100mJ/dot (max) (100 dots) 31mJ/dot (max) (320 dots)
Pulse duration	Up to 15 ms	Up to 15 ms
Emission frequency	Up to 1,5 Hz	Up to 1,5 Hz
Intended Use	The Er:Yag Glass 1540 nm Fractional Laser Handpiece is intended for use in: coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.	The Palomar Lux1540 Handpiece is intended for use in: Coagulation of soft tissue; Skin resurfacing procedures; Treatment of melasma and striae; Treatment of acne scars and surgical scars.

H)IPL Handpiece

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
Classification	GEX 21 CFR 878.4810, ONF 21 CFR 878.4810	GEX, FTC	GEX, FTC, HHR, LNK
Source	Pulsed light Xenon lamp	Pulsed light Xenon lamp	Pulsed light fluorescence lamp
Emission spectrum	400 – 1.200 nm	400 – 1.000 nm	420 – 950 nm
Spot dimension	1; 3; 5; 8 cm2	8 cm2	3; 6 cm2
Standard filters	500-550-580-620-755 nm	530; 550; 580; 620 nm	420; 515; 540; 570; 780 nm
Max energy per pulse	200 J	250 J	180 J
Fluence (max)	30 J/cm2	30 J/cm2	30 J/cm2
Pulse duration (max)	From 1 to 20 ms	5 - 50 ms	10 - 50 ms
Emission frequency (max)	1 Hz	1 Hz	2 - 4 Hz
Pause between one pulse train and the next	From 5 to 500 ms	From 5 to 100 ms	-
Intended Use	IPL 400-1200 nm handpiece is indicated for: * The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, inelasma, and ephelides (freckles). · The treatment of cutaneous lesions including warts, scars and striae. · The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider		420-950 nm Acne Module AFT Handpiece The Advanced Fluorescence Technology (AFT) 420-950 nm Acne Module handpiece (with and without contact-cooling) is indicated for: * The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, inelasma, and ephelides (freckles). · The treatment of cutaneous lesions including warts, scars and striae. · The treatment of benign cutaneous vascular lesions including port wine stains,

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>angiomas, poikiloderma of Civatte, leg veins and venous malformations.</p> <ul style="list-style-type: none"> · Use on all skin types (Fitzpatrick I-VI). 		<p>hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.</p> <ul style="list-style-type: none"> · Use on all skin types (Fitzpatrick I-VI).
	<p>IPL 500-1200 nm handpiece is indicated for:</p> <ul style="list-style-type: none"> · The treatment of moderate inflammatory acne (acne vulgaris). * The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. · The removal of unwanted hair to effect stable long-term or permanent hair reduction. · Use on Fitzpatrick skin types I-V. 		<p>515-950 nm SV515 & SVL515 Module AFT Handpieces</p> <p>The Advanced Fluorescence Technology (AFT) 515-950 nm VL515 and SVL515 Module handpieces (with and without contact-cooling) are indicated for:</p> <ul style="list-style-type: none"> · The treatment of moderate inflammatory acne (acne vulgaris). * The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. · The removal of unwanted hair to effect stable long-term or permanent hair reduction. · Use on Fitzpatrick skin types I-V.

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>IPL 550-1200 nm handpiece is indicated for:</p> <ul style="list-style-type: none"> · The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules. * The treatment of cutaneous lesions including warts, scars and striae. · The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The removal of unwanted hair to effect stable long-term or permanent hair reduction. <p>: Use on all skin types (Fitzpatrick I-VI).</p>		<p>540-950 nm VL/PL, VP, and SSR Module AFT Handpieces</p> <p>The Advanced Fluorescence Technology (AFT) 540-950 nm VL/PL, VP, and SSR Module handpieces (with and without contact-cooling) are indicated for:</p> <ul style="list-style-type: none"> · The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules. * The treatment of cutaneous lesions including warts, scars and striae. · The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The removal of unwanted hair to effect stable long-term or permanent hair reduction. <p>: Use on all skin types (Fitzpatrick I-VI).</p>

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>580-1200 nm handpiece is indicated for:</p> <ul style="list-style-type: none"> * The treatment of moderate inflammatory acne vulgaris. * The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). * The treatment of face and body vascular and pigmented lesions. * The treatment of cutaneous lesions, including scars and striae. · The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI). 		<p>570-950 nm SR Module AFT Handpiece</p> <p>The Advanced Fluorescence Technology (AFT) 570-950 nm SR Module handpiece (with and without contact-cooling) is indicated for:</p> <ul style="list-style-type: none"> * The treatment of moderate inflammatory acne vulgaris. * The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). * The treatment of face and body vascular and pigmented lesions. * The treatment of cutaneous lesions, including scars and striae. · The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI).

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>IPL 620-1200 nm handpiece is indicated for:</p> <ul style="list-style-type: none"> * The treatment of tattoos. * The treatment of moderate inflammatory acne vulgaris. * The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait. • The treatment of cutaneous lesions including warts, scars and striae. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. : The removal of unwanted hair and to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tanned skin. 	<p>1. The removal of unwanted hair and to effect stable long-term or permanent hair reduction</p>	<p>650-950 nm HR Module AFT Handpiece The Advanced Fluorescence Technology (AFT) 650-950 nm HR Module handpiece (with and without contact-cooling) is indicated for:</p> <ul style="list-style-type: none"> * The treatment of tattoos. * The treatment of moderate inflammatory acne vulgaris. * The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait. • The treatment of cutaneous lesions including warts, scars and striae. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. : The removal of unwanted hair and to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tanned skin.

Applicant	BIOS	BIOS	ALMA
Device Name	SUPERBIUM	APL MEDICAL SYSTEM	HARMONY XL
510k	---	K072344	K072564
	<p>755-1200 nm handpiece is indicated for:</p> <ul style="list-style-type: none"> * The treatment of tattoos. * The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles). : The treatment of cutaneous lesions including warts, scars and striae. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis. * The treatment of pseudofolliculitis barbae (PFB). · The removal of unwanted hair to effect stable long-term or permanent hair reduction * Use on all skin types (Fitzpatrick I-VI), including tanned skin. 	<p>4. The non-ablative treatment of facial wrinkles, such as, but not limited to:</p> <ul style="list-style-type: none"> · Periocular wrinkles · Perioral wrinkles <p>7. Treatment of vitiligo and psoriasis</p>	<p>780-950 nm SST AFT Module Handpiece The Advanced Fluorescence Technology (AFT) 780-950 nm SST Module handpiece (with contact-cooling) is indicated for:</p> <ul style="list-style-type: none"> * The treatment of tattoos. * The treatment of moderate inflammatory acne vulgaris. · The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles). : The treatment of cutaneous lesions including warts, scars and striae. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. * The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis. * The treatment of pseudofolliculitis barbae (PFB). · The removal of unwanted hair to effect stable long-term or permanent hair reduction * Use on all skin types (Fitzpatrick I-VI), including tanned skin.

VII. Performance data

Biocompatibility testing

SUPERBIUM 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 SUPERBIUM 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.

Usability testing

Usability of the SUPERBIUM have been tested in accordance with the standard EN 60601-1-6:2010

Pre series test

Pre-series tests (see attachment 15_D) have been performed to support the evidence that performances of SUPERBIUM 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, thta SUPERBIUM 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 SUPERBIUM device when compared to the predicate devices.