June 14, 2024

Bios S.r.l.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K241407
Trade/Device Name: Splendor X (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: May 17, 2024
Received: May 17, 2024

Dear Prithul Bom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.14 15:56:22 -04'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241407

Device Name

Splendor X (Alex, Alex2, Nd:YAG, 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 Pseudofolliculitis barbae (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, such as 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 (sunspots), 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.
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, 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, such as 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.

Electronic Submission Template And Resource (eSTAR)

510kSummary - K241407

Complying with 21 CFR 807.92

I. Submitter

Bios S.r.l.
Via Guido Rossa 10/12
20055 Vimodrone (MI) – Italy

Phone: +39 02 27304275
Mobile: +39 391 7461002
Fax: +39 02 27304276
Email: m.deiturbe@biosgroup.eu

Contact Person: Dr. Martina De Iturbe
Date prepared: 11th June 2024

II. Device

Device Proprietary Name:	Splendor X (Alex, Alex^2, Nd: YAG, Alex + Nd: YAG)
Device Common Name:	Powered laser surgical instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Regulatory Class:	II
Product Code:	GEX

III. Predicate/Reference Device

The substantial equivalence is based on the following Predicate Device:

Trade Name	Product Code and classification regulation	Manufacturer	510(k) Number
Family of Square Epil (Alex, Alex2, Nd:YAG, Alex+Nd:YAG)	GEX 21 CFR 878.4810	Bios S.r.l.	K161632

The Predicate device has been evaluated by the manufacturer as adequate for the equivalence comparison purposes and it has been detected using the best practices for selecting the predicate device. The predicate device has been firstly identified on the basis of the same intended use and the regulatory framework and basic administrative information (classification, medical device class, product code, and applicable federal regulation etc..) that are the same as the subject device.
Secondary, a predicate device identifying well-established safety and performance testing has been preferred to others with lower information availability. The predicate device is currently marketed in

the US and all the documentation is available to support the equivalence since Bios is the manufacturer of the predicate device as well.
In the end, a predicate device with a negligible rate of serious malfunctions/serious injuries/deaths, without unmitigated safety issues and no recalls has been chosen.

Furthermore, the following Reference Device has been identified to support the difference in the technological characteristics between the subject device and the selected predicate device.

Trade Name	Product Code and classification regulation	Manufacturer	510(k) Number
GentleMax Pro Plus	GEX 21 CFR 878.4810	Candela Corporation	K201111

IV. Device Description

The Splendor X (Alex, Alex^2, Nd:YAG, Alex + Nd: YAG), hereinafter referred to as "Splendor X", is a laser equipped with one or two solid-state laser sources.
The 4 configurations 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). In this configuration the two wavelengths can act only individually, simultaneous operations are not allowed. This configuration works with three different modes: only with Alex source, only with Nd:YAG source or in the BlendX mode. With the BlendX mode, an initial pulse with Alexandrite source is followed automatically, without overlapping in time, by another pulse of the Nd:YAG source.

This device is intended for medical use only.

V. Indications 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 Pseudofolliculitis barbae (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, such as 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.
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, 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, such as 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).

VI. Comparison of technological characteristics with the predicate and reference devices

The Splendor X device and its predicate device are based on the same technological principle of two solid-state laser emission (Alexandrite and Nd:YAG). The two laser sources wavelength are intended for the same indications for use.

The subject and predicate devices are based on the following same technological elements, such as, same laser sources, wavelengths, delivery system, power supply, cooling system, optic, user interfaces and display screen. Both the subject device and the predicate share the same operating principles, such as energy, repetition rate, available spot sizes.

The subject device includes an energy check port that was not included in the predicate device. For this reason, a reference device is selected to support the full equivalence comparison. Any other difference does not raise any new or modified safety and/or effectiveness questions due to the similarities to the predicate device.

Table 1: Predicate Device SE comparison

Item for comparison	**Splendor X (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Subject device**	**Family of Square Epil (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Predicate device K161632**
General/Regulatory Information		
Manufacturer	Bios S.r.l.	Bios S.r.l.
510(k) number	Subject of this submission	K161632

Item for comparison	Splendor X (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Subject device	Family of Square Epil (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Predicate device K161632
Device Classification Name	Powered laser surgical instrument	Powered laser surgical instrument
Regulation number	21 CFR 878.4810	21 CFR 878.4810
Product Code	GEX	GEX
Regulation Medical Specialty	General & Plastic Surgery	General & Plastic Surgery
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Classification	Class II	Class II
Indications 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 Pseudofolliculitis barbae (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, such as 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: • Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of Pseudofolliculitis barbae (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.

Item for comparison	Splendor X (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Subject device	Family of Square Epil (Alex, Alex^2, Nd:YAG, Alex+Nd:YAG) Predicate device K161632
	• Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, 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, such as 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).	• Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, 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).
Laser Class	4	4
Laser source	Alexandrite (Alex) Nd:YAG	Alexandrite (Alex) Nd:YAG
Spot size	Square: 2mm, 3mm, 5 mm, 10mm, 14mm, 18mm, 20mm, 24mm, 27mm; Round: 2mm, 3mm, 5 mm, 10mm, 14mm, 18mm, 20mm, 24mm, 26mm, 30 mm	Square: 2mm, 3mm, 5 mm, 10mm, 14mm, 18mm, 20mm, 24mm, 27mm; Round: 2mm, 3mm, 5 mm, 10mm, 14mm, 18mm, 20mm, 24mm, 26mm, 30 mm

The subject device has the same technical features of the predicate excepting for the energy check port that was not introduced at the time of the predicate submission. This difference is supported by the equivalence with the reference device.
The Splendor X and the GentleMax Pro Plus share the same regulatory classification, similar indications for use and technological characteristics included the handpiece power port access.

Table 2: Reference Device SE comparison

Item for comparison	Splendor X (Alex, Alex2, Nd:YAG, Alex+Nd:YAG) Subject device	GentleMax Pro Plus Reference device K201111	Equivalence and/or difference
Indications 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 Pseudofolliculitis barbae (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, such as 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.	1064nm: 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 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.	Same

	• 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. • Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and for yeast Candida Albicans, etc.) The Alexandrite 755 laser is intended for: • Temporary hair reduction.	Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe 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 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.) 755nm: 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, such as 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).	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 vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).	
Manufacturer	Bios S.r.l.	Candela Corp.	NA
Device Classification Name	Powered laser surgical instrument	Powered laser surgical instrument	Same
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Product Code	GEX	GEX	Same
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Same
Review Panel	General & Plastic Surgery	General & Plastic Surgery	Same
Classification	Class II	Class II	Same

Energy check port	Yes	Yes (“Calibration Port”)	Similar. Both the subject device and the reference device are equipped with a handpiece housing, integrated in the chassis, that allows the user to check the emitted energy.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation of the Splendor X device was conducted, and documentation was provided in accordance with the FDA's Guidance for Industry and FDA Staff *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""* and the recognized consensus standard ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

The Splendor X device is categorized as follow:

- Category: "surface device"
- Contact: "intact skin"
- Contact duration: "limited" (≤24h).

The biocompatibility testing included the following endpoints:

- Cytotoxicity
- Sensitization
- Irritation

Electrical safety and electromagnetic compatibility (EMC)

The Splendor X has been tested and it is compliant with the recognized consensus standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2: Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests;
- IEC 60601-2-22: Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1: Safety of laser products - Part 1: Equipment classification and requirements

Software Verification and Validation Testing and Cybersecurity

Software verification and validation testing were conducted, and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff *"Content of Premarket Submissions for Device Software Functions"*. The software for this device was verified according to IEC 62304.

Cybersecurity information has been provided according to FDA's Guidance for Industry and FDA Staff *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".*

The results of the Verification and Validation performed with Splendor X met the applicable requirements.

Usability Testing

Usability of the Splendor X have been tested and it is compliant with the recognized consensus standards:

- EN IEC 60601-1-6: Medical electrical equipment — Part 1-6: General requirements for the basic safety and essential performance — Collateral standard: Usability;
- IEC 62366-1: Medical devices - Application of usability engineering to medical devices

Animal and Clinical Study

Animal and clinical studies were not necessary to demonstrate that the performances are equivalent to the predicate devices.

VIII. Conclusion

Based on the comparison analysis with the predicate device (K161632), the non-clinical data that support the safety and effectiveness of the Splendor X and the hardware and software verification and validation that demonstrate that the device performs as intended in the specified use conditions, it can be concluded that Splendor X performs comparably to the predicate device that is currently marketed for the same intended use and to the reference device, when referred the technological difference.