**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 16, 2017

Dentsply Sirona
Karl Nittinger
Senior Manager, Corporate Regulatory Affairs
221 West Philadelphia Street Suite 60
York, Pennsylvania 17404

Re: K170500
Trade/Device Name: SIROLaser Advance+
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, ILY
Dated: February 18, 2017
Received: February 21, 2017

Dear Karl Nittinger:

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 -S

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)*
K170500

Device Name: SIROLaser Advance+

Indications for Use *(Describe)*

The SIROLaser Advance+ is intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty ; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: The SIROLaser Advance+ is indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: The SIROLaser Advance+ is intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

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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Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

**SECTION 5. 510(k) SUMMARY**
**for**
SIROLaser Advance+

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: 15 May 2017

2. Device Name:

- Proprietary Name: SIROLaser Advance+
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
- CFR Number: 21 CFR 878.4810
- Device Class: Class II
- Product Code: GEX (*Powered Laser Surgical Instrument*)
  ILY ( *Lamp, Infrared, Therapeutic Heating*)

3. Predicate Device:

The predicate devices for the SIROLaser Advance+ are:

| **Primary Predicate Device Name** | **510(k)** | **Company Name** |
|---|---|---|
| Epic 10 | K121286 | Biolase Technology, Inc. |

| **Additional Predicate Devices** | **510(k)** | **Company Name** |
|---|---|---|
| SIROLaser Advance | K103753 | Sirona Dental Systems GmbH |
| THOR VR Single Diode Laser Treatment Probe | K070024 | THOR International |

## 4. Description of Device:

The SIROLaser Advance+ is a solid state laser in which laser energy is generated by internal diodes. The laser output energy of the device is in the infrared and red spectra at wavelengths of 970 nm and 660nm, respectively. The output settings of the SIROLaser Advance+ can be adjusted by the user and also features preset operating modes which are designed to correspond with its proposed surgical, periodontic, and endodontic applications.

SIROLaser Advance+ primarily consists of a laser control unit with graphical touch screen user interface, a laser handpiece, and single-use, disposable, "EasyTip" laser fiber guides (for surgical applications), as well as, reusable "MultiTip" light guides (for non-contact, low-power, "soft laser" applications). The laser control unit contains the 970 nm and 660 nm laser diodes, electronic hardware, touchscreen graphical user interface, and software to control the laser functionality.

The SIROLaser Advance+ handpiece assembly consists of an internal handpiece body with laser activation finger switch. The handpiece includes a removable stainless steel outer sleeve which can be cleaned and sterilized between patient procedures. The SIROLaser Advance+ is also offered with an optional wireless footswitch.

## 5. Indications for Use:

The SIROLaser Advance+ is intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty ; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: The SIROLaser Advance+ is indicted for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: The SIROLaser Advance+ is intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

6. Substantial Equivalence:

The SIROLaser Advance+ has the same intended use as the predicate device. Both the SIROLaser Advance+ and the predicate device are intended as powered laser surgical instruments as well as to provide topical heating to soft tissues for therapeutic purposes under 21 CFR 878.4810 and 21 CFR 890.5500, respectively.

The SIROLaser Advance+ and the predicate device both generate laser energy via solid state LED technology. As do the predicate devices, the SIROLaser Advance+ emits laser light energy in both the infrared and red spectra.

The SIROLaser Advance+ and the predicate device are operated for surgical applications using handpieces to which single-use laser fiber tips are attached. For low-level laser therapy applications, both the SIROLaser Advance+ and the predicate device offer non-contact handpieces.

Detailed comparison of the intended use, indications for use, and design of the SIROLaser Advance+ and the predicate devices is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

| **Proposed Device**<br>**SIROLaser Advance+** | **Primary Predicate Device**<br>**Epic 10**<br>**(K121286)** | **Predicate Device**<br>**SIROLaser Advance**<br>**(K103753)** | **Predicate Device**<br>**THOR VR Single Diode Laser Treatment Probe**<br>**(K070024)** |
|---|---|---|---|
| **Surgical indications for Use:** | | | |
| Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: | Incision, excision, vaporization, ablation and coagulation of oral tissues including marginal and inter-dental gingiva and epithelial lining of free gingiva and the following specific indications: | Intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: | **N/A** |
| frenectomy; frenotomy; | frenectomy; frenotomy | frenectomy; frenotomy; | |
| biopsy; operculectomy; | excisional and incisional biopsies; operculectomy; | biopsy; operculectomy; | |
| implant recovery; | implant recovery; | implant recovery; | |
| gingivectomy; gingivoplasty; | gingivectomy; gingivoplasty; | gingivectomy; gingivoplasty; | |
| gingival troughing; | gingival troughing for crown impressions; | gingival troughing; | |
| crown lengthening; | soft tissue crown lengthening; | crown lengthening; | |
| hemostasis of donor site; | hemostasis and coagulation; | hemostasis of donor site; | |

Table 6.1 (continued): Indications for Use

| **Proposed Device**<br>**SIROLaser Advance+** | **Primary Predicate Device**<br>**Epic 10**<br>**(K121286)** | **Predicate Device**<br>**SIROLaser Advance**<br>**(K103753)** | **Predicate Device**<br>**THOR VR Single Diode Laser Treatment Probe**<br>**(K070024)** |
|---|---|---|---|
| **Surgical Indications for Use (continued)** | | | |
| removal of granulation tissue; | incision and drainage of abscess; | removal of granulation tissue; | **N/A** |
| laser assisted flap surgery; | | laser assisted flap surgery; | |
| debridement of diseased epithelial lining; | | debridement of diseased epithelial lining; | |
| incisions and draining of abscesses; | | incisions and draining of abscesses; | |
| tissue retraction for impressions; | tissue retraction for impressions; | tissue retraction for impressions; | |
| papillectomy; vestibuloplasty; | oral papillectomies; vestibuloplasty; | papillectomy; vestibuloplasty; | |
| excision of lesions; | | excision of lesions; | |
| exposure of unerupted/partially erupted teeth; | exposure of unerupted teeth; | exposure of unerupted/partially erupted teeth; | |
| removal of hyperplastic tissues; | | removal of hyperplastic tissues; | |
| treatment of aphthous ulcers; | | treatment of aphthous ulcers; | |
| leukoplakia; | leukoplakia; | leukoplakia; | |
| pulpotomy; pulpotomy as adjunct to root canal therapy; | pulpotomy; pulpotomy as an adjunct to root canal therapy; | pulpotomy; pulpotomy as adjunct to root canal therapy; | |
| fibroma removal; gingival incision and excision; | fibroma removal; gingival incision and excision; | fibroma removal; gingival incision and excision; | |
| treatment of canker sores; herpetic ulcers of the oral mucosa; | treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; | treatment of canker sores; herpetic ulcers of the oral mucosa; | |
| laser soft tissue curettage; | laser soft tissue curettage; | laser soft tissue curettage; | |
| reduction of gingival hypertrophy. | reduction of gingival hypertrophy. | reduction of gingival hypertrophy. | |
| **Laser Periodontic Indications for Use** | | | |
| laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal pocket; | laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal pocket; | laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal pocket; | **N/A** |
| sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); | sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility); | sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); | |

Table 6.1 (continued): Indications for Use

| **Proposed Device**<br>**SIROLaser Advance+** | **Primary Predicate Device**<br>**Epic 10**<br>**(K121286)** | **Predicate Device**<br>**SIROLaser Advance**<br>**(K103753)** | **Predicate Device**<br>**THOR VR Single Diode Laser Treatment Probe**<br>**(K070024)** |
|---|---|---|---|
| **Tooth Whitening** | | | |
| Light activation for bleaching materials for teeth whitening; | Light activation for bleaching materials for teeth whitening; | **N/A** | **N/A** |
| Laser-assisted whitening/bleaching of teeth. | Laser-assisted whitening/bleaching of teeth. | | |
| **Low Level Laser Therapy** | | | |
| Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles. | Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains, and minor back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle. | **N/A** | Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or temporary relaxation of muscles. |

Table 6.2: Design

| **Proposed Device**<br>**SIROLaser Advance+** | **Primary Predicate Device**<br>**Epic 10**<br>**(K121286)** | **Predicate Device**<br>**SIROLaser Advance**<br>**(K103753)** | **Predicate Device**<br>**THOR VR Single Diode Laser Treatment Probe**<br>**(K070024)** |
|---|---|---|---|
| **Laser Classification** | | | |
| 970 nm Laser: Class IV | 940 nm Laser: Class IV | 970 nm Laser: Class IV | 660 nm Laser: Class II |
| 660 nm Laser: Class II | | | |
| **Laser Type** | | | |
| Solid state diode laser | Solid state diode laser | Solid state diode laser | Solid state diode laser |
| **Laser Wavelength** | | | |
| 970 nm (- 10 nm/+ 15 nm) | 940 nm (+/- 10 nm) | 970 nm (+/- 15 nm) | 660 nm |
| 660 nm (+/- 5 nm) | | | |

Table 6.2 (continued): Design

| **Proposed Device**<br>**SIROLaser Advance+** | **Primary Predicate Device**<br>**Epic 10**<br>**(K121286)** | **Predicate Device**<br>**SIROLaser Advance**<br>**(K103753)** | **Predicate Device**<br>**THOR VR Single Diode Laser Treatment Probe**<br>**(K070024)** |
|---|---|---|---|
| **Optical Power** | | | |
| **970 nm**:<br>0.2 W – 7.0 W (CW)<br>14 W (peak optical power)<br>**660 nm**:<br>25 mW, 50 mW, 100 mW | 10 W | 7.0 W (max.) (CW)<br>14 W (peak optical power) | 30 mW, 75 mW, 200 mW |
| **Emission Modalities** | | | |
| • Continuous Wave<br>• Chopped (1 Hz – 10 kHz)<br>• Peak Pulse (1.5 kHz – 20 kHz) | • Continuous Wave<br>• Pulse Modulation (up to 20 kHz) | • Continuous Wave<br>• Chopped (1 Hz – 10 kHz)<br>• Peak Pulse (up to 20 kHz). | • Continuous Wave |
| **Pulse Duration** | | | |
| Chopped Mode:<br>10 µsec. to 0.99 sec.<br>Peak Pulse Mode: 23 µsec. | 10 µsec. to 20 msec. | Chopped Mode:<br>10 µsec. to 0.99 sec.<br>Peak Pulse Mode: 23 µsec. | N/A |
| **Aiming Beam Wavelength and Power** | | | |
| 660 nm (+/- 5 nm)<br>1 mW (max.) | 625 nm to 670 nm<br>1 mW (max.) | 635 nm to 650 nm<br>1mW (max.) | N/A |
| **Optical Fiber Surgical Tips** | | | |
| Fiber Diameter:<br>200 µm, 320 µm | Fiber Diameter:<br>200 µm, 300 µm, 400 µm | Fiber Diameter:<br>200 µm, 320 µm | N/A |
| • Single-use tips.<br>• Integral laser fiber.<br>• Plastic proximal connection hub.<br>• Bendable stainless steel cannula.<br>• Provided sterile (sterilized by ethylene oxide). | • Single-use tips.<br>• Integral laser fiber.<br>• Plastic proximal connection hub.<br>• Bendable cannula.<br>• Provided non-sterile. | • Single-use tips.<br>• Laser fiber assembled with tip by user.<br>• Plastic proximal connection hub.<br>• Bendable stainless steel cannula.<br>• Provided non-sterile. | N/A |
| **Laser Handpiece** | | | |
| • Handpiece connected by flexible optical fiber to control unit.<br>• Finger switch laser activation.<br>• Removable, sterilizable stainless steel outer sleeve. | • Handpiece connected by flexible optical fiber to control unit.<br>• Handpiece is sterilizable. | • Handpiece connected by flexible optical fiber to control unit.<br>• Finger switch laser activation.<br>• Removable, sterilizable outer sleeve. | N/A |
| **Laser Therapy Light Guides** | | | |
| Curved light guides;<br>4 mm, 8mm diameter. | • Optional deep tissue handpiece with adjustable spot-size spacer;<br>• Optional whitening / contour handpiece. | N/A | • Single diode laser probe.<br>• Diode laser cluster probe. |

Table 6.2 (continued): Design

| **Activation Method** | | | |
|---|---|---|---|
| • Handpiece finger switch.<br>• Optional wireless foot switch. | • Wireless footswitch. | • Handpiece finger switch.<br>- Optional wireless foot switch. | • Probe activation finger switch. |
| **Laser Control Unit Dimensions** | | | |
| 182 mm x 197 mm x 189 mm | 145 mm x 112 mm x 165 mm | 182 mm x 197 mm x 189 mm | Unknown. |
| **Laser Control Unit User Interface** | | | |
| Color touch screen graphical user interface. | Color touch screen graphical user interface. | Color touch screen graphical user interface. | Manual switches and buttons. |

7. Non-Clinical Performance Data

The Testing to verify the performance requirements of the SIROLaser Advance+ was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification:

- Testing to verify the conformity of the proposed SIROLaser Advance+ with the requirements of IEC 60601-1: (*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).
- Testing to verify the conformity of the proposed SIROLaser Advance+ with the requirements of IEC 60601-1-2: (*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility*).
- Testing to verify the conformity of the proposed SIROLaser Advance+ to IEC 60825-1 (*Safety of laser products – Part 1: Equipment classification and requirements*).
- Testing to verify the performance of the proposed SIROLaser Advance+ according to IEC 60601-2-22: (*Medical electrical equipment Part 2: Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment*).
- Usability study conducted in conformity with IEC 62366 (*Medical devices – Application of usability engineering to medical devices*).
- Biocompatibility assessment of patient contacting components of the proposed device according to the requirements ISO 10993-5 (*Biological evaluation of medical devices Part 5: Tests for cytotoxicity*).
- Validation of the device's software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*).

8. Clinical Performance Data

No human clinical data was included to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject SIROLaser Advance+. The subject device has the identical intended use as the identified legally marketed predicate device. The subject device has the same intended use and incorporates the same technologies as the identified predicate devices.

Performance and biocompatibility data are included in this premarket notification to demonstrate the performance of the subject SIROLaser Advance+ against its design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.