March 8, 2018

Dentsply Sirona
Karl Nittinger
Senior Manager, Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K180044
Trade/Device Name: SIROLaser Blue
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: March 8, 2018
Received: March 8, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180044

Device Name
SIROLaser Blue

Indications for Use *(Describe)*
The SIROLaser Blue is intended for:
(970 nm and 445 nm): 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 (970 nm and 445 nm): The SIROLaser Blue is indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy (660 nm and 970 nm): The SIROLaser Blue 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. 510(k) SUMMARY
for
SIROLaser Blue

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: March 8, 2018

2. Device Name:

- Proprietary Name: SIROLaser Blue
- 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 and reference devices identified relating to the substantial equivalence of the SIROLaser Blue are:

Primary Predicate Device Name	**510(k)**	**Company Name**
SIROLaser Advance+	K170500	Dentsply Sirona

Secondary Predicate Device Name	**510(k)**	**Company Name**
SIROLaser Advance	K103753	Sirona Dental Systems GmbH

4. Description of Device:

The SIROLaser Blue is a solid state laser device in which laser energy is generated by internal diodes. The laser output energy of the device is in the infrared, red, and blue spectra at wavelengths of 970 nm, 660nm, and 445 nm respectively. The output settings of the SIROLaser Blue can be adjusted by the user.

SIROLaser Blue primarily consists of a laser control unit with graphical touch screen user interface, a laser handpiece, single-use, disposable, "EasyTip" laser fiber guides (for surgical applications), and reusable "MultiTip" light guides (for non-contact, low-power, "soft laser" applications). The laser control unit contains the 970 nm, 660 nm, and 445 nm laser diodes, electronic hardware, touchscreen graphical user interface, and software to control the laser functionality.

The SIROLaser Blue 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 Blue is also offered with an optional wireless footswitch.

5. Indications for Use:

The SIROLaser Blue is intended for:

(970nm and 445nm): 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 (970nm and 445nm): The SIROLaser Blue is indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy (660nm and 970nm): The SIROLaser Blue 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 subject SIROLaser Blue has the same intended use as the predicate device. Both the SIROLaser Blue and the primary 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 subject SIROLaser Blue and the primary predicate device (K170500) both generate laser energy via solid state LED technology. As does the primary predicate device (K170500), the subject SIROLaser Blue emits laser light energy in both the infrared and red spectra.

In addition to laser energy in the infrared and red spectra, the subject SIROLaser Blue also emits laser energy in the blue (445 nm) spectrum. The secondary predicate SIROLaser Advance (K103753) is included in the technological comparison because published performance bench testing which verified the equivalency of the cutting efficiency of the 445 nm laser wavelength compared to that of the 970 nm laser wavelength is included in this premarket notification to support substantial equivalence. The bench test performance verification was conducted utilizing the subject SIROLaser Blue (445 nm) and the secondary predicate SIROLaser Advance (K103753) device (970 nm) and compared soft tissue cutting performance.

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

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

Table 6.1: Indications for Use

Proposed Device **SIROLaser Blue**	**Primary Predicate Device** **SIROLaser Advance+** **(K170500)**	**Secondary Predicate Device** **SIROLaser Advance** **(K103753)**
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:	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:	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;	frenectomy; frenotomy;	frenectomy; frenotomy;
biopsy; operculectomy;	biopsy; operculectomy;	biopsy; operculectomy;
implant recovery;	implant recovery;	implant recovery;
gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;	gingivectomy; gingivoplasty;
gingival troughing;	gingival troughing;	gingival troughing;
crown lengthening;	crown lengthening;	crown lengthening;
hemostasis of donor site;	hemostasis of donor site;	hemostasis of donor site;

Table 6.1 (continued): Indications for Use

Proposed Device **SIROLaser Blue**	**Primary Predicate Device** **SIROLaser Advance+** **(K170500)**	**Secondary Predicate Device** **SIROLaser Advance** **(K103753)**
Surgical Indications for Use (continued)		
removal of granulation tissue;	removal of granulation tissue;	removal of granulation tissue;
laser assisted flap surgery;	laser assisted flap surgery;	laser assisted flap surgery;
debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	debridement of diseased epithelial lining;
incisions and draining of abscesses;	incisions and draining of abscesses;	incisions and draining of abscesses;
tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;
papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;
excision of lesions;	excision of lesions;	excision of lesions;
exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;
removal of hyperplastic tissues;	removal of hyperplastic tissues;	removal of hyperplastic tissues;
treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers;
leukoplakia;	leukoplakia;	leukoplakia;
pulpotomy; pulpotomy as adjunct to root canal therapy;	pulpotomy; pulpotomy as 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 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;
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 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 inability);
Tooth Whitening Indications for Use		
Light activation for bleaching materials for teeth whitening;	Light activation for bleaching materials for teeth whitening;	N/A
Laser-assisted whitening/bleaching of teeth.	Laser-assisted whitening/bleaching of teeth.	N/A

Table 6.1 (continued): Indications for Use

Proposed Device **SIROLaser Blue**	**Primary Predicate Device** **SIROLaser Advance+** **(K170500)**	**Secondary Predicate Device** **SIROLaser Advance** **(K103753)**
Low Level Laser Therapy Indications for Use		
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.	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.	N/A

Table 6.2: Design

Proposed Device **SIROLaser Blue**	**Primary Predicate Device** **SIROLaser Advance+** **(K170500)**	**Secondary Predicate Device** **SIROLaser Advance** **(K103753)**
Laser Classification		
970 nm and 445 nm Laser: Class IV	970 nm Laser: Class IV	970 nm: 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
Laser Wavelength		
970 nm	970 nm	970 nm
660 nm	660 nm	
445 nm		
Optical Power		
970 nm: 0.2 W – 2.0 W (Continuous Wave)	**970 nm**: 0.2 W – 7.0 W (Continuous Wave) 14 W (peak optical power)	**970 nm**: 7.0 W max. (Continuous Wave) 14 W (peak optical power)
660 nm: 25 mW, 50 mW, 100 mW (Continuous Wave)	**660 nm**: 25 mW, 50 mW, 100 mW (Continuous Wave)	
445 nm: 0.2 W – 3.0 W (Continuous Wave)		
• Continuous Wave • Chopped (1 Hz – 10 kHz)	• Continuous Wave • Chopped (1 Hz – 10 kHz) • Peak Pulse (1.5 kHz – 20 kHz)	• Continuous Wavre • Chopped (1 Hz – 10 kHz) • Peak Pulse (up to 20 kHz)
Chopped Mode: 10 µsec. to 0.99 sec.	Chopped Mode: 10 µsec. to 0.99 sec.	Chopped Mode: 10 µsec. to 0.99 sec.
	Peak Pulse: 23 µsec.	Peak Pulse: 23 µsec.

Table 6.2 (continued): Design

Proposed Device **SIROLaser Blue**	**Primary Predicate Device** **SIROLaser Advance+** **(K170500)**	**Secondary Predicate Device** **SIROLaser Advance** **(K103753)**
Aiming Beam		
660 nm 1 mW (max.)	660 nm 1 mW (max.)	635 nm – 650 nm 1 mW (max)
Optical Fiber Surgical Tips		
Fiber Diameter: 200 µm, 320 µm	Fiber Diameter: 200 µm, 320 µm	Fiber Diameter: 200 µm, 320 µm
• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided sterile (sterilized by ethylene oxide).	• Single-use tips. • Integral laser fiber. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided sterile (sterilized by ethylene oxide).	• Single-use tips. • Laser fiber assembled with tip by user. • Plastic proximal connection hub. • Bendable stainless steel cannula. • Provided non-sterile.
Laser Handpiece		
• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable stainless steel outer sleeve.	• Handpiece connected by flexible optical fiber to control unit. • Finger switch laser activation. • Removable, sterilizable outer sleeve.
Laser Therapy Light Guides		
Curved light guides; 4 mm, 8mm diameter.	Curved light guides; 4 mm, 8mm diameter.	N/A
Activation Method		
• Handpiece finger switch. • Optional wireless foot switch.	• Handpiece finger switch. • Optional wireless foot switch.	• Handpiece finger switch. • Optional wireless foot switch.
Laser Control Unit Dimensions		
182 mm x 197 mm x 189 mm	182 mm x 197 mm x 189 mm	182 mm x 197 mm x 189 mm
Laser Control Unit User Interface		
Color touch screen graphical user interface.	Color touch screen graphical user interface.	Color touch screen graphical user interface.

7. Non-Clinical Performance Data

The Testing to verify the performance requirements of the SIROLaser Blue 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 Blue 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 Blue 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 Blue to IEC 60825-1 (*Safety of laser products – Part 1: Equipment classification and requirements*).
- Testing to verify the performance of the proposed SIROLaser Blue 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*).
- Statement confirming that the patient-contacting accessories of the subject SIROLaser Blue are identical to the accessories cleared for use with the predicate device and therefore no new biocompatibility testing was performed to support substantial equivalence.
- Validation of the device's software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*).
- Published bench test data is included which summarize studies conducted utilizing the SIROLaser Blue device comparing the cutting efficiency of the 445 nm laser wavelength (through histological examination of cutting depth and tissue denaturation) with the 970 nm laser wavelength of the secondary predicate device (K103753).

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 Blue. The subject device has the identical intended use as the legally marketed predicate device. The subject device also has the same indications for use and incorporates the same fundamental technology as the predicate devices.

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