November 20, 2019

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

Re: K191865
Trade/Device Name: SmartLite Pro Modular LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ, NTK
Dated: July 31, 2019
Received: August 1, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191865

Device Name
SmartLite® Pro Modular LED Curing Light

Indications for Use *(Describe)*
-For light activated polymerization of dental materials such as composites, luting cements. and sealants using visible light.

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
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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."

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)*
K191865

Device Name
SmartLite® Pro Modular LED Curing Light

Indications for Use *(Describe)*
-For intraoral illumination used upon initial examination of the dental patient and dental transillumination to help locate crown fractures, posterior and anterior caries, and for use as an auxiliary light source for endodontic procedures.

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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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

K191865 - 510(k) SUMMARY
for
SmartLite®Pro Modular LED Curing Light

Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

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

Date Prepared: 18-November-2019

Device Name:

- Proprietary Name: SmartLite®Pro Modular LED Curing Light
- Classification Name: Ultraviolet Activator for Polymerization
  Laser Fluorescence Caries Detection Device
- CFR Number: 872.6070
  872.1745
- Device Class: Class II
- Product Code: EBZ, NTK

Primary Predicate Devices:

Primary Predicate Devices	510(k)	Company Name
Palmlight 10	K061341	CAO Group, Incorporated
Microlux Transilluminator	K062961	AdDent, Incorporated

Reference Device:

Reference Device	510(k)	Company Name
Bluephase® Style	K110756	Ivoclar Vivadent, Incorporated

Description of Device:

Dentsply Sirona intends to market the proposed SmartLite®Pro Modular LED Curing Light with an indications for use as a dental curing light as well as a dental illuminator.

Based upon the FDA Guidance, *"Bundling Multiple Devices or Multiple Indications in a Single Submission Guidance for Industry and Food and Drug Administration Staff Document*", issued on June 22, 2007, bundling, as found in the case of the proposed devices, is acceptable, because one of the bundled devices is an accessory to the other. In the proposed bundled device, two attachments utilize the same handpiece in order to function.

The proposed SmartLite®Pro Modular LED Curing Light is a cordless pen-style, LED light polymerization and illumination device for use by dental professionals in dental offices or dental laboratories.

The proposed SmartLite®Pro Modular LED Curing Light is characterized by:

- Small size and lightweight ergonomic design.
- Compact cordless design with convenient handling features and exchangeable battery pack.
- Individually adjustable LED tips, rotatable by 360°.
- LED tip design providing excellent intra-oral access.
- Polymerization area (optic effective cross-sectional area) of 10 mm in diameter.
- Up to 10 seconds curing time per activation with audible signal at start and end of cycle.
- Advanced heat management system limiting LED tip temperature.
- Exchangeable tips for:
  - curing of CQ initiated materials.
  - curing of materials with initiators absorbing in the violet range.
  - intraoral illumination and dental transillumination.

Indications for Use:

- For light activated polymerization of dental materials such as composites, luting cements, and sealants using visible light.
- For intraoral illumination used upon initial examination of the dental patient and dental transillumination to help locate crown fractures, posterior and anterior caries, and for use as an auxiliary light source for endodontic procedures.

Substantial Equivalence:

Technological Characteristics

Table 5.1 compares the proposed device with the primary predicate device, Palmlight 10(K061341).

Table 5.1		
Proposed Device SmartLite®Pro Modular LED Curing Light (K191865)	**Primary Predicate Device** Palmlight 10 (K061341)	**Differences**
Indications for Use	**Indications for Use:**	
For light activated polymerization of dental materials such as composites, luting cements, and sealants using visible light.	For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.	Narrowing for the indications for use of the proposed device. With the proposed device, polymerization of dental materials if performed using visible light only where the primary predicate uses visible and near-UV light. Proposed device does not include dental adhesives.
Features:	**Features:**	**Differences**
Cordless design with exchangeable battery pack. The exchangeable battery packs can be charged on a charging base.	Option to be used cordless (battery powered) or corded (connected to mains) Rechargable lithium ion batteries for the charging base so the charging base may be used un-corded	The proposed device does not offer corded back up. The proposed device can only be powered using the exchangeable battery pack. The proposed device's charging base can only be used while connected to the mains.
Individually removable and rotatable LED tips	360° rotating LED tip	Both the proposed device and primary predicate device LED tips can be rotated. The primary predicate device tip cannot be removed.
Up to 10 seconds curing time per activation with audible signal at start and end of cycle	- Adjustable timer (5, 10, 15, 20 sec) with countdown display - Audible signals confirm button presses to select the mode and time, and every 5 sec during the curing process	The proposed device does not offer multiple options for curing cycle duration.
Software limits LED tip temperature. Provides audible warnings when device tip reaches critical temperature and turns off.	Software monitors the temperature of the unit and the unit turns off when the temperature at the wand tip reaches 48°C to minimize exposure of personnel and patients to excessive temperatures	The proposed device has audible warnings when the device reaches the maximum temperature compared to the primary predicate which just turns off.
Wide spectral output range from 405-480 nm	Wide spectral output range from 400-460 nm	The proposed device has a higher maximum wavelength than its primary predicate Palmlight 10.

Proposed Device SmartLite®Pro Modular LED Curing Light (K191865)	**Reference Device** Bluephase® Style (K110756)	**Reason for Reference Device**
Wide spectral output range from 405-480 nm	Wide spectral output range from 430-490 nm.	To address the wider spectral output generated by the proposed SmartLite®Pro Modular LED Curing Light, in comparison to its primary predicate Palmlight 10, reference device, Bluephase® Style was added.

Table 5.2 compares the proposed device with the primary predicate device, Microlux Transilluminator (K062961).

Table 5.2

Proposed Device SmartLite®Pro Modular LED Curing Light	**Primary Predicate Device** Microlux Transilluminator (K062961)	**Differences**
Indications for Use	**Indications for Use:**	
For intraoral illumination used upon initial examination of the dental patient and dental transillumination to help locate crown fractures, posterior and anterior caries, and for use as an auxiliary light source for endodontic procedures.	The Microlux Transilluminator is a device used upon initial examination of the dental patient to help locate crown fractures, posterior and anterior caries. The microlux Transilluminator is a screening device used to help locate caries and crown fractures. It also functions as an auxiliary light source to aid in operative procedures and preventive dentistry.	The intraoral illumination of endodontic access and root canal orifices in the indications for use of the subject device are proposed as a more narrowly scoped use which is within the cleared indications for use of the primary predicate device as an “auxiliary light source to aid in operative procedures and preventive dentistry”.
Features:	**Features:**	**Differences**
Cordless design with exchangeable battery pack. The exchangeable battery packs can be charged on a charging base.	Option to be used cordless (battery powered) or corded (connected to mains) Rechargeable lithium ion batteries for the charging base so the charging base may be used un-corded	The proposed device does not offer corded back up. The proposed device can only be powered using the exchangeable battery pack. The proposed device’s charging base can only be used while connected to the mains.

Table 5.2 (continued)		
Proposed Device SmartLite®Pro Modular LED Curing Light	**Primary Predicate Device** Microlux Transilluminator (K062961)	**Differences**
Features:	**Features:**	**Differences**
LED tip with 1.5 mm output diameter	Available glass light guides with 2 mm and 3 mm output diameter.	The proposed device has a tip with a single output diameter.
Two output powers to visualize anterior or posterior dental anatomy	Single output power to visualize dental anatomy	The proposed device has the option for use of two output powers.

Non-Clinical Performance Data.

Performance testing of the SmartLite®Pro Modular LED Curing Light was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence. The exchangeable tip used in the test is identified.

The following testing was conducted using the exchangeable tip as identified within the testing, as applicable:

- Testing to verify Output Power (Cure Tip). Internal test method and acceptance criteria.
- Testing to verify Output Power (PolyCure Tip). Internal test method and acceptance criteria.
- Testing to verify Output Power (Illuminate Tip). Internal test method and acceptance criteria.
- Testing to compare Depth of Cure of Cure Tip, PolyCure Tip, and primary predicate (K061341) per ISO 4049*: (Dentist – Polymer-based restorative materials).*
- Testing to compare Irradiance over Distance of Cure Tip, PolyCure Tip, and primary predicate (K061341). Internal test method and acceptance criteria.
- Testing to verify the conformity of the proposed SmartLite®Pro Modular LED Curing Light 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 SmartLite®Pro Modular LED Curing Light 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 SmartLite®Pro Modular LED Curing Light with the requirements of IEC 80601-2-60: (*Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of dental equipment).*

- Testing to verify the conformity of the proposed SmartLite®Pro Modular LED Curing Light with the requirements of IEC 60601-1-6: (*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Usability).*
- 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 SmartLite®Pro Modular LED Curing Light according the requirements of ISO 10993-5 (*Biological evaluation of medical devices Part 5: Tests for cytotoxicity*).
- Validation of the devices' software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*).

The performance of SmartLite®Pro Modular LED Curing Light satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Clinical Performance Data.

No data from human clinical studies has been included to support the substantial equivalence of the SmartLite® Pro Modular LED Curing Light.

Conclusion Regarding Substantial Equivalence

The SmartLite® Pro Modular LED Curing Light is a light polymerization and illumination device for use by dental professionals. The SmartLite® Pro Modular LED Curing Light has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the primary predicate Palmlight 10 cleared under premarket notification K061341 and the primary predicate Microlux Transilluminator cleared under premarket notification K062961.

The results of the performance testing, combined with the design and intended use comparison with the primary predicate devices, support substantial equivalence.