December 22, 2022

Dent4You AG
Dr. Tricia Cregger
Global Regulatory Affairs Manager
Bahnhofstrasse 2
Heerbrugg, 9435
SWITZERLAND

Re: K223142
Trade/Device Name: Coltolux Comfort LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: October 3, 2022
Received: October 4, 2022

Dear Dr. Tricia Cregger:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223142

Device Name

Coltolux Comfort LED Curing Light

Indications for Use *(Describe)*

The Coltolux Comfort LED Curing Light is indicated for the polymerization of intra- and extraoral dental restorations fabricated from materials (commonly referred to as visible light cured dental restoratives and/or composites and/or dental adhesives) that contain Camphorquinone as the photoinitiator.

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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510(k) Summary

Prepared on: 2022-10-03

Contact Details

K223142

21 CFR 807.92(a)(1)

Applicant Name	Dent4You AG
Applicant Address	Bahnhofstrasse 2 Heerbrugg 9435 Switzerland
Applicant Contact Telephone	330-916-8904
Applicant Contact	Dr. Tricia Cregger
Applicant Contact Email	tricia.cregger@coltene.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Coltolux Comfort LED Curing Light
Common Name	Ultraviolet activator for polymerization
Classification Name	Activator, Ultraviolet, For Polymerization
Regulation Number	872.6070
Product Code	EBZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K040551	Coltolux LED Curing Light	EBZ

Device Description Summary

21 CFR 807.92(a)(4)

The proposed Coltolux Comfort LED Curing Light (Coltolux Comfort) is used for the polymerization of light-cured resin materials used in dental restorations. The Coltolux Comfort incorporates a focused high-power LED to produce light in the "deep blue" spectrum (wavelength 440 - 470 nm) for activating Camphorquinone (CQ) photo-initiators. The device is utilized by placement of the lens within close proximity to the surface of the material to be cured, activation of the curing light via the pushbutton switch, and retention of the tip near the dental material until the composite is cured.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Coltolux Comfort LED Curing Light is indicated for the polymerization of intra- and extraoral dental restorations fabricated from materials (commonly referred to as visible light cured dental restoratives and/or composites and/or dental adhesives) that contain Camphorquinone as the photoinitiator.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the Coltolux Comfort LED Curing Light are the same as the indications for use of the predicate device, the Coltolux LED Curing Light (K040551).

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Technological Comparison

21 CFR 807.92(a)(6)

The Coltolux Comfort LED Curing Light (subject device) and the Coltolux LED Curing Light (predicate device) are both LED curing lights for dental composite material. The indications for use and technological characteristics are substantially equivalent with only minor

differences, including the mechanism of battery charging and the light intensity. These minor differences do not constitute a new intended use or raise different questions of safety and effectiveness compared with the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing was conducted to verify that the proposed Coltolux Comfort Curing Light meets the requirements as defined in FDA Guidance Document "Dental Curing Lights - Premarket Notification [510(k)]" and in accordance with IEC 60601-1 and IEC 60601-1-2. Software verification and validation of the device were conducted in accordance with the FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Performance Testing – Bench, of this Premarket Submission, contains detailed information regarding the proposed Coltolux Comfort Curing Light including testing protocols, test objectives, test articles, test methods and procedures, and acceptance criteria.
Non-clinical tests performed to establish substantial equivalence to the identified predicate device included light output uniformity and dropoff testing, peak wavelength testing (ISO 10650:2018), irradiance output (ISO 10650:2018), depth of cure, endurance testing, light attenuation through barrier sleeve, light shield filtration, life testing, duty cycle (IEC 60601-1:2012), EMC (IEC 60601-1-2:2014), electromagnetic disturbances (IEC 60601-1-2:2014), and photobiological safety (IEC 62471:2006).

Not Applicable

Based on the non-clinical performance data the proposed Coltolux Comfort Curing Light is as safe, as effective, and performs as well as or better than the predicate device Coltolux LED Curing Light (K040551, 21 CRF 872.6070, product code EBZ).