KMIHH Ltd
Or Ramot
9 Hamovil Str.,
Kfar-Saba, 4442411 ISRAEL

April 1, 2019

Re: K181597
Trade/Device Name: Le'Pen
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: January 16, 2019
Received: January 22, 2019

Dear Or Ramot:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.04.01 14:01:11 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K181597

Device Name
Le'pen

Indications for Use *(Describe)*
Source of illumination for curing photo-activated dental restorative materials and adhesives.

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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# *Appendix B*
# K181597

## *510(k) Summary*

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92(a).

### *807.92(a)(1) Submitter Information*

KMIHH LTD (kii.am)

9 HaMovil Str.,

Kfar-Sava 4442411,

Israel

Contact Person: Or Ramot

Telephone: +972-3-3030-163

Date of writing: 2017-11-02

### *807.92(a)(2) Name & Classification*

Trade name: Le'pen

Common Name: Dental Curing Light

Classification Name(s): Ultraviolet Activator for Polymerization - 872.6070

Classification Number: EBZ

### 807.92(a)(3) Predicate device

Ultradent Valo Cordless K110582

Common Name: Dental Curing Light

Classification Name(s): Ultraviolet Activator for Polymerization - 872.6070

Classification Number: EBZ

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### *807.92(a)(4) Device Description*

The *Le'pen* is a battery-powered cordless unit designed for curing VLC materials whose initiator systems are sensitive to light in the 385-480 nm wavelength range of the visible spectrum. The unit is based on violet and blue LED (light emitting diode) technology for light generation in the desired wavelength and Li-Ion rechargeable batteries.

The *Le'pen* includes:

- A cordless rechargeable handpiece with a focusing lens focusing light emitted from a multi LED package tip and controlled by built-in control electronics
- A base unit that plugs into main power as the handpiece stand and charger
- A cap at probe tip to block light scattering
- Disposable disinfectant barrier sleeves on the tip probe
- User manual

### *807.92(a)(5) Intended Use(s)*

Aka ***Indication For Use***

Source of illumination for curing photo-activated dental restorative materials and adhesives.

### *807.92(a)(6) Technological Characteristics and Substantial Equivalence*

The *Le'pen* is substantially equivalent to K110582 in intended use, operation, wavelength range, and light source.

We believe the similarity of the *Le'pen* to the legally marketed predicate devices and the performance data provided support the claim for equivalence of the *Le'pen* to the Valo Cordless.

| | Predicate Device<br>Valo Cordless (Ultradent) | Le'pen<br>(KMIHH LTD) |
|---|---|---|
| 510(k) Number | K110582 | K181597 (pending) |
| Common Name | Activator, ultraviolet for polymerization | Activator, ultraviolet for polymerization |
| Product Code | EBZ | EBZ |
| CFR | 872.6070 | 872.6070 |
| Indications for Use | Source of illumination for curing photo-activated dental restorative materials and adhesives. | Source of illumination for curing photo-activated dental restorative materials and adhesives. |
| Where Used | Dental offices | Dental offices |
| Target Population | Health care professionals | Health care professionals |
| Anatomical Site | Oral cavity | Oral cavity |

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| | | |
|---|---|---|
| Light source | 4 broad blue LEDs for photoinitiated curing of dental materials | 4 broad blue LEDs for photoinitiated curing of dental materials<br><br>4 white light LEDs for general illumination |
| Wavelength Range [nm] | 385-490 | 385-490 |
| Power [watts/cm$^2$] | 1200 | 1200 |
| Cooling System | Convection cooled | Convection cooled |
| Materials | Aluminum body, glass lens | Aluminum body, glass lens |
| Battery Type | Lithium or Lithium-Ferrite-Polymer | Lithium-Manganese |
| Sterility | Non-sterile | Non-sterile |
| Weight | 150g | 150g |
| Rotating Tip | No | No |
| Built in Meter | No | No |
| Replaceable Bulb or Tip | No | No |
| Multiple Curing Modes / Durations | Yes | Yes |

Similarities between the Le'pen and Valo Cordless:

- The Le'pen has identical indications for use as the predicate device, the Valo Cordless.
- The Le'pen has the same mode of action as the predicate device, the Valo Cordless (i.e. photo-polymerization of monomers and oligomers to polymers via activation of photoinitiators).
- The Le'pen has equivalent performance characteristics as the predicate device (Valo Cordless) as both products use the same light source (LED).
- The Le'pen has equivalent performance characteristics as the predicate device (Valo Cordless) as both products provide the user with various curing durations / settings.
- The Le'pen and the Valo provide a nearly equivalent wavelength spectrum range.
- The Le'pen is substantially equivalent to the predicate device (Valo Cordless) as both devices shown compliance with IEC 60601-1 and ADA 48 (i.e. ISO 10650-1).
- The Le'pen and the Valo Cordless are both equivalent in their design; both medical devices are Li-ion battery operated cordless devices with an aluminum body construction.
- The Le'pen and the Valo Cordless have identical mass.

Difference between the Le'pen and Valo Cordless:

- The Le'pen uses an LED package containing 8 LEDs, while the predicate device (Valo Cordless) utilizes an LED package containing 4 LEDs.
    - This does not raise any substantial equivalence concerns as the total energy emitted

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is very similar between the devices, as shown during benchtop testing. Additionally, benchtop testing confirmed adequate depth of cure, radiometric power, and spectral distribution of the subject device and confirmed substantial equivalence to the predicate device.
    - Therefore, the Le'pen remains substantially equivalent to the Valo Cordless.
- The Le'pen contains a white light mode, whereas the Valo Cordless does not.
    - This does not raise any substantial equivalence concerns as the white light is classified as a class I medical device (CRF 872.4630, dental operating light).
    - It should be noted that other 510(k) cleared dental curing lights contain a white light mode: K152936 - Sirius Max Diode Curing Light and K170101 - Valiant Curing Light. These device are mentioned for reference purpose only.
    - Therefore, the Le'pen remains substantially equivalent to the Valo Cordless.
- The Le'pen contains a Violet mode, whereas the Valo Cordless does not.
    - Many photopolymerizable dental materials contain lower wavelength photoinitiators (between 385nm and 410nm). Therefore, this violet mode is simply another curing mode and does not introduce any additional safety or efficacy concerns and does not make the subject device not substantially equivalent.
    - Therefore, the Le'pen remains substantially equivalent to the Valo Cordless.
- Slight variations in "radiometric power" and "light duration" exist between the Le'pen and Valo Cordless.
    - Functionality testing (e.g. Depth of Cure testing) confirmed that the Le'pen provides satisfactory depth of cure results for various dental composite resins. Therefore, any slight differences in "radiometric power" and "light duration" do not yield any efficacy or safety concern as the Le'pen cures composite effectively. Therefore, the Le'pen remains substantially equivalent to the Valo Cordless.
- The Le'pen has a "soft start mode", whereas the Valo Cordless does not.
    - Functionality testing (e.g. Depth of Cure testing) confirmed that the Le'pen provides satisfactory depth of cure results for various dental composite resins on all Le'pen settings. Therefore, the "soft start mode" does not yield any efficacy or safety concern as the Le'pen cures composite effectively. Therefore, the Le'pen remains substantially equivalent to the Valo Cordless.
    - It should be noted that other 510(k) cleared dental curing lights contain a "soft start" or "ramp" mode: K152936 - Sirius Max Diode Curing Light and K170101 - Valiant Curing Light. These device are mentioned for reference purpose only.

The Le'pen and Valo Cordless share similar intended uses, technical characteristics, specifications, and features. Kiiam concludes that the Le'pen is substantially equivalent to the Valo Cordless, and that any of the discussed differences between the two devices do not raise any additional safety or efficacy concerns that would necessitate further testing.

### *807.92(b)(1-3) Brief Discussion of the Nonclinical & Clinical Testing*

The following nonclinical tests were performed to evaluate device safety and efficacy as well as offer

a comparison to the predicate device.

1. Radiometric Power Testing
    a. Testing concluded that the Le'pen provided similar to or greater radiometric power compared to the predicate device, Valo Cordless. These results, in conjunction with "Depth of Cure" testing, supports a designation of substantial equivalence as similar functionality is provided by the Le'pen and Valo Cordless.
2. Spectral Irradiance Testing
    a. Testing verified the spectrum emitted from the Le'pen matches the intended specifications. Comparing the spectrum results between the Le'pen and Valo Cordless supports a substantial equivalent designation as both curing lights emit nearly identical wavelength spectrums for curing dental materials.
3. LED Lifetime
    a. Testing verified device longevity through simulating LED use over a three year period. This test supports product efficacy and longevity.
4. Depth of Cure
    a. Testing was performed in-line with the ISO 4049:2009 standard which is commensurate with depth of cure testing described in the FDA Curing Light Guidance. Results confirm that satisfactory depth of cure was achieved for several dental composite resins and shades. Results support device efficacy as well as substantial equivalence as compliance with the ISO 4049:2009 standard was observed.
5. Thermal Generation
    a. Testing verified that the device does not reach unsafe temperatures during typical use and simulated worst-case scenarios. Results support device safety as well as substantial equivalence as the predicate device exhibits thermal safety during routine use.
6. Software Validation
    a. Testing confirmed the device's software is functioning properly. This test supports product efficacy and safety.
7. Electrical Safety and Electromagnetic Compatibility
    a. Testing confirmed that the device is safety and in compliance with relevant electrical safety and electromagnetic compatibility standards (IEC 60601-1 and IEC 60601-1-2).

Based on the longstanding history of dental curing lights, significant published literature confirming safety and efficacy of LED-based dental curing lights, and satisfactory benchtop testing, Kiiam concludes that clinical testing is not deemed necessary.

### *Conclusion*

The Le'pen is substantially equivalent to the Valo Cordless (K110582) in intended use and operation; both medical devices use LEDs as the source of light for curing dental materials. Benchtop testing, and existing literature on LED-based dental curing lights, supports substantial equivalence of the

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Le'pen to the Valo Cordless.