August 4, 2023

Good Doctors Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K223507
Trade/Device Name: CL-DP40 (Dr's Light PRIME), CL-DP40 (Dr's Light CHOICE)
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: June 5, 2023
Received: June 5, 2023

Dear Priscilla Chung:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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)*

K223507

Device Name
CL-DP40 (Dr's Light PRIME)/ CL-DP40 (Dr's Light CHOICE)

Indications for Use *(Describe)*
CL-DP40 (Dr's Light PRIME)/CL-DP40 (Dr's Light CHOICE)is a hand held LED polymerization light intended to cure dental composites 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.

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K223507

510(k) Summary

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 11/21/2022

1. Submitter

Good Doctors Co., Ltd.
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283 Bupyeong-daero, Bupyeong-gu, Incheon
21315, Republic of Korea

2. U.S Agent/Contact Person

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3. Device

- Trade Name: CL-DP40 (Dr's Light PRIME)/ CL-DP40 (Dr's Light CHOICE)
- Common Name: Ultraviolet Activator
- Classification Name: Ultraviolet Activator for Polymerization
- Product Code: EBZ
- Classification regulation: 21CFR 872.6070

4. Predicate Device:

- Primary Predicate Device:
  Dr's Light 2 by Good Doctors Co., Ltd. (K173157)
- Reference Predicate Devices:
  Bluephase by Ivoclar Vivadent (K033520)
  LED Turbo by Apoza Enterprise Co., Ltd. (K040618)

5. Description:

This unit is a battery type wireless LED curing light. User can adjust light intensity and time by selecting six program modes. Both of Dr's Light PRIME and Dr's Light Choice

are characterized by high power intensity, slim head height, large irradiation area (12mm), adjustable intensity power, highly readable color touch screen, 360˚ twistable head and big capacity of the battery.

6. Indication for use:

CL-DP40 (Dr's Light PRIME)/CL-DP40 (Dr's Light CHOICE)is a hand held LED polymerization light intended to cure dental composites using visible light.

7. Basis for Substantial Equivalence

The subject device CL-DP40 (Dr's Light PRIME) / CL-DP40 (Dr's Light CHOICE) incorporates the same intended use with the predicate devices. The devices are similar in device design and the structure.
The technical specifications between the subject device and the primary predicate device are identical. The difference is that the subject device has 6 modes and the primary predicate device has 7 modes. However, we believe this difference does not raise a questions in safety and performance since the technical specifications between the devices are the same.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device 1**	**Reference Predicate Device 2**
510(K) #	N/A	K173157	K033520	K040618
Device Name	CL-DP40 (Dr's Light PRIME) CL-DP40 (Dr's Light CHOICE)	Dr's Light 2	Bluephase	LED Turbo
Manufacturer	Good Doctors Co., Ltd.	Good Doctors Co., Ltd.	Ivoclar Vivadent	Apoza Enterprise Co., Ltd.
Product Code	EBZ	EBZ	EBZ	EBZ
Intended for Use	CL-DP40 (Dr's Light PRIME)/ CL-DP40 (Dr's Light CHOICE) is a hand held LED polymerization light intended to cure dental composites using visible light.	Dr's Light 2 is a hand held LED polymerization light intended to cure dental composites using visible light.	Bluephase® is a hand held LED polymerization light intended to cure dental composites using visible light.	The LED Turbo is a dental curing light that is designed for use in the optic polymerization of dental resins and activation of bleaching materials.
Device Design 1. Operational Modes 2. Light Source 3. Power Source 4. Wave length range 5. Accessories	1. 6 Modes 2. 8W LED 3. Battery 3.7V 4. 400nm-490nm (Dr's Light PRIME) 440nm-490nm (Dr's Light Choice) 5. Guide Tip, Shield	1. 7 Modes 2. 8W LED 3. Battery 3.7V 4. 400nm-490nm 5. Guide Tip, Shield	1. 3 Modes 2. 8W LED 3. Battery 7.2V 4. 430nm-490nm 5. Guide Tip, Shield	1. 3 Modes 2. 5W LED 3. Battery 7.2V 4. 440nm-490nm 5. Guide Tip, Cone
Composition of Materials	Glass Guide Tip	Glass Guide Tip	Glass Guide Tip	Glass Guide Tip

Technical specification 1. Light intensity 2. Peak Wavelength 3. Depth of cure	Max 1600W/cm2 460nm & 405nm 2.3mm(avg.)	Max 1600W/cm2 460nm & 405nm 2.3mm(avg.)	Max 1100mW/cm2 460nm 2.1mm(avg.)	Max 1100mW/cm2 460nm 2.1nm(avg.)
Electrical Safety	IEC60601-1	IEC 60601-1	-	-
EMC & EMI	IEC 60601-1-2	IEC 60601-1-2	-	-

8. Non-Clinical Testing

- Depth of curing test
- Electrical Safety and EMC tests in accordance with IEC 60601-1 and 60601-1-2

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, CL-DP40 (Dr's Light PRIME)/CL-DP40 (Dr's Light CHOICE) has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate similar design,
* have the same technological characteristics

Based on the similarities, we conclude that the subject device is substantially equivalent to the predicate devices.