July 22, 2021

Shenzhen Kaiyan Medical Co Ltd
Alain Dijkstra
CEO
40A Fuxin Road Fuyong Subdistrict BaoAn District
Shenzhen, Guangdong 518000
China

Re: K203214
Trade/Device Name: DemarkQ WOW, DemarkQ POP
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: OLP
Dated: June 11, 2021
Received: June 15, 2021

Dear Alain Dijkstra:

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,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203214

Device Name
DemarkQ, Model: DemarkQ WOW (PB-B), DemarkQ POP (SJ-72)

Indications for Use *(Describe)*
The DemarkQ is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.

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

K203214

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Company: SHENZHEN KAIYAN MEDICAL CO LTD

Establishment Registration Number: 3011644607

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Contact Person (including title): Alain Dijkstra（CEO）

Email: alaindijkstra@kaiyanmedical.com

Application Correspondent:

Contact Person: Alain Dijkstra

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2. Subject Device Information

Type of 510(k): Traditional

Common Name: WOW LED therapy lamp / POP LED therapy lamp

Classification Name: Over-The-Counter Powered Light Based Laser For Acne

Trade Name: DemarkQ, Model: DemarkQ WOW(PB-B), DemarkQ POP(SJ-72)

Review Panel: General & Plastic Surgery

Product Code: OLP

Regulation Number: 878.4810

Regulation Class: 2

3. Predicate Device Information

	Predicate Device 1	Predicate Device 2	Predicate Device 3
Sponsor	LED Technologies, Inc.	Medtek Skincare, LLC	Uvbiotek, LLC
Device Name and Model	dpl® SpotLite	Poly Clear	LED Light Therapy Device, model: KN-7000C
510(k) Number	K183118	K183708	K180900
Product Code	OLP	OLP	OLP
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	II	II	II

4. Device Description

The DemarkQ, Model: DemarkQ WOW(PB-B), DemarkQ POP(SJ-72) are over-the counter light emitting diode (LED) panel device, that emits energy for use in dermatology for the treatment of mild to moderate inflammatory acne. The devices use two types of LEDs: 630nm red and 415nm blue. The device operated only by one key, both wavelengths will be emitted at the same time when it be turned on. The treatment time is controlled by the user. There are no user settings or adjustments required.

The device's components include the main device which containing the LED treatment module, USB power cord and goggles.

5. Intended Use / Indications for Use

The DemarkQ is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.

6. Test Summary

The DemarkQ, Model: DemarkQ WOW(PB-B), DemarkQ POP(SJ-72) have been evaluated the safety and performance by lab bench testing as following:

- IEC 60601-1:2005/(R)2012 and A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11 Edition 2.0 2015-01, Medical electrical equipment -- part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- IEC 60601-2-57 Edition 1.0 2011-01 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304 Edition 1.1 2015-06, Medical device software - Software life cycle processes
- ISO 10993-5 Third edition, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device		Predicate Device 1	Predicate Device 2	Predicate Device 3	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD		LED Technologies, Inc.	Medtek Skincare, LLC	Uvbiotek, LLC	--
Trade Name	DemarkQ		dpl SpotLite	Poly Clear	LED Light Therapy Device	--
Model	DemarkQ WOW (PB-B)	DemarkQ POP(SJ-72)	-	KN-7000C	-	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne		Over-The-Counter Powered Light Based Laser For Acne	Over-The-Counter Powered Light Based Laser For Acne	Over-The- Counter Light Based Laser for Acne	SE
510(k) Number	Applying		K183118	K183708	K180900	--
Product Code	OLP		OLP	OLP	OLP	SE
Intended Use / Indications for Use	The DemarkQ is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.		The dpl® SpotLite is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.	The Poly Clear combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the light spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	The LED Light Therapy Device is indicated for the treatment of mild to moderate inflammatory acne	SE
Power Supply	Power by: 2 x (3.7Vdc, 2700 mAh lithium	Power by: 3.7Vdc, 1500 mAh lithium	Not publicly available	100-240V, 50/60Hz±2%, 300VA (Mains Connected)	Adaptermodel number: LXCP12-005200DEG, Input: 100-240V a.c. 50/60Hz,	SE Note 1

	battery, 10.26Wh) Adapter Input: 100-240Vac, 50/60Hz Adapter Output: DC 5V, 2A Main unit input: DC 5V, 2A	battery, 10.26Wh Adapter Input: 100-240Vac, 50/60Hz Adapter Output: DC 5V, 2A Main unit input: DC 5V, 2A			0.5Amax. Output: 5V d.c. 2A Main unit: input: 5V d.c. 2A/Internal battery: 3.6Vd.c. 2200mAh Internal battery specification: CR18650-22F 3.6V d.c. 2200mAh	
Wavelengths	630nm±10nm 415nm±10nm		415nm, 630nm	633±10nm 417±10nm	Red light 633nm±10nm Blue light 417nm±10nm	SE
Irradiance source	LEDs		LEDs	No publicly available	LEDs	SE
Number of LEDs	112 each panel	Total 72	Not publicly available	Red: 910 Blue: 910	Red: 48 Blue: 48 Total: 96	SE Note 2
Irradiance (mW/cm²)	Red: 5 Blue: 25	Red: 25 Blue: 25±5	Not publicly available	Combo Red/Blue head: Red: 30m±10 Blue: 20m±10	Red light 45±5 Blue light 25±5	SE Note 2
Time range and frequency	3 minutes per treatment. Can be used daily.		3 minutes per treatment	No publicly available	3 minutes per skin area. Can be used daily.	SE
EMC	IEC 60601-1-2		IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Safety	IEC 60601-1, IEC 60601-2-57 IEC 60601-1-11 IEC 62471		IEC 60601-1	IEC60601-1 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	SE

Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	--	ISO 10993-1, ISO 10993-5, ISO 10993-10	SE

Comparison in Detail(s):

Note 1:

Although the “Power Supply” is different from the predicate devices, but they all complied with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Number of LEDs” and “Irradiances” are different from the predicate devices, But they are all within the scope of comparing device parameters and they all complied with the IEC 60601-1, IEC 60601-1-2, IEC 62471 and IEC 60601-2-57 safety standards’ requirements. So, these differences will not raise any safety or effectiveness issue.

Final Conclusion：

After an analysis of the safety indications, intended uses, performance, and other technological characteristics, the Sponsor believes that no significant differences exist between the new device and the predicate devices and no new issues of safety or effectiveness are raised. Thus, the subject device DemarkQ, Model: DemarkQ WOW(PB-B), DemarkQ POP(SJ-72) are Substantial Equivalence to the predicate devices K183118, K183708 and K180900.

8. Date of the summary prepared: June 11, 2021