January 2, 2025

Dongguan Laiguang Electronic Technology Co.,Ltd.
Jiangxiang Wu
General Manager
Room201,NO.64,DongkangRoad,DalingshanTown
Dongguan, Guangdong 523820
China

Re: K242789
Trade/Device Name: Bestqool LED Therapy Device (LMK-001,LMK-004,LMK-005,LMK-006)
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: OHS, OLP
Dated: September 13, 2024
Received: September 16, 2024

Dear Jiangxiang Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.01.02 18:54:45 -05'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242789

Device Name
Bestqool LED therapy device Model: LMK-001LMK-004LMK-005LMK-006

Indications for Use *(Describe)*
This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.

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.

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"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."

K242789 - 510(k) Summary

1. Submitter Information:

Dongguan Laiguang Electronic Technology Co., Ltd.
Address:Room201,NO.64,DongkangRoad,DalingshanTown,Dongguan, Guangdong,China.
Tel :+86-18824627447
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2. Contact Person:

Jiangxiang Wu (General Manager)

3. Date prepared:

January 1, 2025

4. Device Information:

Device Name: Bestqool LED therapy device
Model: LMK-001、LMK-004、LMK-005、LMK-006
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name: Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP)
Product Code: OHS ,OLP
Regulatory Class: Class II

5. Predicate Device Information:

Device Name: LED facial light therapy mask (Model: HK207), Flexible LED light therapy (Model: HK209)
Manufacturer: NINGBO HESI ELECTRIC CO., LTD.
510(k) Number: K200983
The predicate device has not been subject to a design-related recall.

6. Device Description:

The Bestqool LED therapy devices, available in models LMK-001, LMK-004, LMK-005, and LMK-006, differ only in their appearance color to cater to user preferences. The device is designed as a foldable arch shape and is equipped with 200 LED beads. Despite the color variations, the device structure and functional parameters remain identical across all models,which uses specific wavelengths of light to manage aesthetic conditions. This device does not come into contact with the body; users should lie under the device treatment area during use.The device is powered by an AC adapter.
This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.

7. Indications for Use:

This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.

8. Predicate Device Comparison

The following table compares the intended use and technological characteristics of the subject and predicate device.

Table 1 Comparison Between the Subject and Predicate Device

	Subject Device **Bestqool LED therapy device** **Models: LMK-001、LMK-004、LMK-005、LMK-006**	**Predicate Device** **LED facial light therapy mask (Model: HK207), Flexible LED light therapy (Model: HK209)** **K200983**	**Comment**
Product Code	OHS, OLP	OHS, OLP, ILY	Similar
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Class	Class II	Class II	Same
Indication for Use	This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.	The LED FACIAL LIGHT THERAPY MASK (Model: HK207) is intended to: - The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. - The device emitting energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles. The FLEXIBLE LED LIGHT THERAPY (Model: HK209) is intended to: - The device emitting energy in the blue is intended to reduce the mild to moderate inflammatory acne vulgaris. - The device emitting energy in the red and infrared spectrum is intended for the treatment of full-face wrinkles - The device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.	The proposed device's indications for use are similar to those of the predicate device HK207 model

Power Source(s)	Input:100-240Vac, 0.6A, 50/60Hz	Input: 100-240Vac, 2.0 A, 50/60Hz	Same
Wavelength(s)(nm)	Blue :415nm±10nm Red :635nm±10nm Near-infrared :850nm±10nm	465nm, 640nm, 880nm	Same
Irradiances (mW/cm2)	7.5mw/cm2±25%	6.5 mW/cm2	Same
Treatment Dose (J/cm2)	13.5 J/cm2±25%	11.7 J/cm2	Same
Treatment time	4 times a week 30-60 minutes session 4 weeks	3 times a week for 30min. 4 weeks	Similar

Based on the comparison table above, the proposed device and predicate device have the same indications for use, working principle, wavelengths and conformance standards, etc. Furthermore, the proposed device's irradiance and radiation dose are similar to those of the predicate device. Minor differences do not raise new questions of safety and effectiveness and these differences in technological characteristics may be evaluated through performance testing.

9. Summary of Non-Clinical Performance Testing:

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the device per the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020, Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.
- IEC 60601-1-11:2015 +A1:2020, 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 60601-1-2:2014+A1:2020, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests standard for EMC.
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601- 1:2005, AMD1:2012, AMD2:2020,Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.Software Verification and Validation Testing

Software verification & validation was provided in accordance with 2023 FDA guidance: *Content of Premarket Submissions for Device Software Functions.* The documentation level for the subject device is Basic Documentation Level.

Performance Testing and Use Life Verification

- The subject device has a use-life of 2-years.

Bench test: Wavelength test , Irradiance test , Treatment dose test.

Clinic test :N/A

10. Conclusion:

The proposed device has technological characteristics that are similar to the predicate devices, and when

compared to the predicate devices it does not raise new types of questions regarding the safety and efficacy for the above indications for use. Performance testing discussed above was conducted with the device to show that it can perform safely and effectively. The proposed device is considered to be substantially equivalent to the predicate device K200983.