July 14, 2021

Ningbo Hesi Electric Co., Ltd
Ms. Cassie Lee
Guangzhou GLOOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District,
Guangzhou, Guangdong 511495
China

Re: K200983
Trade/Device Name: LED facial light therapy mask (Model: HK207), Flexible LED light therapy (Model: HK209)
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, ILY
Dated: April 2, 2020
Received: April 14, 2020

Dear Cassie Lee:

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)*
K200983

Device Name
LED FACIAL LIGHT THERAPY MASK (Model: HK207), FLEXIBLE LED LIGHT THERAPY (Model: HK209)

Indications for Use *(Describe)*
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.

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 of K200983

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

Sponsor Name: NINGBO HESI ELECTRIC CO., LTD

Establishment Registration Number: 3009784099

Address: NO.818-23-156 Qiming Rd, Yinzhou, Ningbo City Zhejiang, CHINA

Postal code: 315000

Contact name: MA LULU (General Manager)

Tel: 15825567078

Fax: 0574-88300553

E-mail: 463415782@qq.com

2. Date of the summary prepared: July 13, 2021

3. Application Correspondent:

Contact Person: Ms. Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

4. Subject Device Information

Type of 510(k): Traditional

Classification Name: Light Based Over-The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP); Lamp, Infrared, Therapeutic Heating (ILY)

Trade Name: LED FACIAL LIGHT THERAPY MASK (Model: HK207), FLEXIBLE LED LIGHT THERAPY (Model: HK209)

Review Panel: General & Plastic Surgery

Product Code: OHS, OLP, ILY

Regulation Number: 890.5500, 878.4810

Regulatory Class: II

5. Predicate Device Information

Sponsor	Biophotas, Inc	Biophotas, Inc
Device Name and Model	BioPhotas Celluma^3	BioPhotas Celluma^3
510(k) Number	K152280	K171323
Product Code	ILY, OHS, OLP	OHS
Regulation Number	890.5500, 878.4810	878.4810
Regulation Class	II	II

6. Device Description

LED FACIAL LIGHT THERAPY MASK (Model: HK207) is a home use wearable LED phototherapy device designed to fit the contours of the target areas of the anatomy, covered with a biocompatible material, which uses specific wavelengths of light to manage aesthetic conditions. This device produces light in the blue light (465nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. The red light (640nm) in combination with infrared light (880nm) is intended to improve the appearance of wrinkles.

FLEXIBLE LED LIGHT THERAPY (Model: HK209) is a highly shapeable LED panel designed to fit the contours of the target areas of the anatomy, covered with a biocompatible material, which uses specific wavelengths of light to manage aesthetic conditions. This device produces light in the near-infrared region of the spectrum (880nm) intended to provide topical heating to tissue for temporary pain relief. Blue light (465nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. Red light (640nm) in combination with infrared light (880nm) is intended to improve the appearance of wrinkles.

7. Intended Use / Indications for Use

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.

8. Comparison to predicate device

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

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Verdict**
Company	Ningbo Hesi Electronic Co., Ltd	Biophotas, Inc	Biophotas, Inc	--
Trade Name	LED FACIAL LIGHT THERAPY MASK (Model: HK207), FLEXIBLE LED LIGHT THERAPY (Model: HK209)	BioPhotas Celluma^3	BioPhotas Celluma^3	--
510(k) Number	K200983	K152280	K171323	--
Product Code	OHS, OLP, ILY	ILY, OHS, OLP	OHS	SE
Intended Use / Indications for Use	The LED FACIAL LIGHT THERAPY MASK (Model: HK207) is intended to: - The device emitting energy in	The BioPhotas Celluma^3 is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue	The BioPhotas Celluma^3 is intended to emit energy in the visible and infrared region of	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
	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-	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 blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. The Celluma^3 is intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital wrinkles.	the spectrum for use in the treatment of full face wrinkles.	

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
	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.			
Regulation Number	890.5500, 878.4810	890.5500, 878.4810	878.4810	SE
Regulation Name	Light Based Over-The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP); Lamp, Infrared, Therapeutic	Light Based Over-The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP); Lamp, Infrared, Therapeutic	Light Based Over – The Counter Wrinkle Reduction (OHS)	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
	Heating (ILY)	Heating (ILY)		
Regulatory Class	Class II	Class II	Class II	SE
Treatment areas	Entire Face and body	Entire Face and body	Whole Face	SE Note 3
Intended population	Adult	Adult	Adult	SE
Power Source(s)	Input: 100 – 240Vac, 2.0 A, 50/60Hz	110 – 120V	110-120V	SE Note 2
Wavelength(s)(nm)	465nm, 640nm, 880nm	465nm, 640nm, 880nm	Red: 640nm±25nm NIR: 880nm±50nm	SE
Irradiances (mW/cm^2)	6.5 mW/cm^2	6.5 mW/cm^2	6.5 mW/cm^2	SE
Treatment Dose (J/cm^2)	11.7 J/cm^2	11.7 J/cm^2	11.7 J/cm^2	SE
Treatment time	3 times a week for 30 min. 4 weeks	3 times a week for 30 min. 4 weeks	3 treatments per week (1800 seconds) 4 weeks	SE
The distance between the LEDs to treatment surface	For model: HK207 0.5-3cm For model: HK209 10 cm	As closed to the skin	As closed to the skin	SE
Irradiation area	HK207: 510 cm^2 HK209: 890 cm^2	820 cm^2	15” x 8”	SE Note 3
Electrical safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although the Intended Use is slightly different from the predicate devices in the description, we can find that the subject device emits the same wavelengths and the same intended purpose as the predicate device. So, the slight differences will not raise any safety or effectiveness issues.

Note 2:

Although the “Power Source(s)” of the subject device is a little different from the predicate devices, they are all compliant with IEC 60601-1 and IEC 60601-2-57 requirements and the range of power source can be safely used in the USA area. So, the differences will not raise any safety or effectiveness issues.

Note 3:

Although the “Treatment area” is a little different from the predicate devices, it’s just the factor depends on the shape of the product which will not affect the safety and effectiveness, and they all compliant with IEC 60601-2-57 requirements. So, the differences will not raise any safety or effectiveness issues.

9. Test Summary

1) Bench test:

The LED FACIAL LIGHT THERAPY MASK (Model: HK207) and FLEXIBLE LED LIGHT THERAPY (Model: HK209) have been evaluated the safety and performance by lab bench testing as following:

- ISO 10993-5:2009, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility).
- ISO 10993-10 2010, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility).
- IEC 60601-1: 2005+A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance .
- IEC 60601-1-2: 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility.
- IEC 60601-1-11 (Edition2.0): 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 60601-2-57 (First Edition): 2011 for use in conjunction with IEC 60601-1:2005, Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of non-

laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

2) Clinic test

N/A

10. Conclusion：

The subject device K200983 “LED FACIAL LIGHT THERAPY MASK (Model: HK207), FLEXIBLE LED LIGHT THERAPY (Model: HK209)” is Substantial Equivalent to the predicate devices K152280 and K171323.