

510(k) Summary of K220168

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 878.4810.

1. Submitter's Information

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2. Subject Device Information

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)

Trade Name: Skin Care Beauty Mask

Model Name: MJ-06

Review Panel: General & Plastic Surgery

Product Code: OHS, OLP

Regulation Number: 878.4810

Regulatory Class: II

3. Predicate Device Information

Sponsor: SHENZHEN KAIYAN MEDICAL CO LTD

Trade Name: Aduro Light Beauty Mask, Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)

510(K) Number: K202390

Review Panel: General & Plastic Surgery

Product Code: OHS, OLP

Regulation Number: 878.4810

Regulation Class: II

4. Device Description

The Skin Care Beauty Mask (Model: MJ-06) is a facemask-shaped device, which makes use of specific light spectral characteristics and directly applies light onto the face skin surface. The Skin Care Beauty Mask can emit two different kinds of wavelengths. The blue light (465nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. Red light (640nm) is intended to improve the appearance of wrinkles. There are 150 LED lights with a center wavelength of 465nm and 150 LED lights with a center wavelength of 640nm, and the energy provided by each mode is 30mw/cm². The user wears the mask on their face for the treatment, and the device will shut down automatically after finishing a 5-minute treatment or 10-minute treatment selected.

5. Intended Use / Indications for Use

The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.

6. Test Summary

Skin Care Beauty Mask (Model: MJ-06) has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Date
ANSI AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	07/09/2014

Standards No.	Standard Title	Version	Date
IEC 60601-1-11	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	Edition 2.0 2015-01	06/27/2016
IEC 60601-2-57	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	Edition 1.0 2011-01	03/16/2012
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Edition 4.0 2014-02	09/17/2018
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	12/23/2016
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition 2010-08-01	07/26/2016

7. Comparison to predicate device and conclusion

The subject device is very similar in design principle, indications for use, functions, materials, and applicable performance, when compared to the above models of the K202390 predicate. Differences

between the subject device and predicate do not raise new types of questions with regard to the safety and effectiveness of the subject device for the proposed indications for use.

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	SHENZHEN KAIYAN MEDICAL CO LTD	SHENZHEN KAIYAN MEDICAL CO LTD	--
Trade Name	Skin Care Beauty Mask	Aduro Light Beauty Mask	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)	Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based OverThe Counter Wrinkle Reduction (OHS)	--
510(k) Number	K220168	K202390	--
Product Code	OHS, OLP	OHS, OLP	SE
Intended Use / Indications for Use	The Skin Care Beauty Mask (Model: MJ-06) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.	For MK-66O, MK-66USBO, MK-02O: The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically indicated to treat full face wrinkles and/or mild to moderate acne.	SE
Wavelengths	Red: 640nm±10nm Blue: 465nm±10nm	Red: 640nm±10nm Blue: 465nm±10nm	SE
Power supply	Adapter: Input: 100-240Va.c., 50/60Hz, 0.5A Output: 5.0Vd.c., 2.0A	For model MK-66O, MK-66USBO: 3.7Vdc 2600mAh Lithium battery Adapter for charging only: Input: 100- 240Vac; Output: 5Vdc, 2A. For model MK-02O: 3.7Vdc 2600mAh Lithium battery	SE
Irradiance source	LEDs	LEDs	SE
Treatment time	5 or 10 minutes/day, 3 times per	10minutes/day, 3 times per week	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
	week		
Power Density (mw/cm ²)	30mW/cm ²	30mW/cm ²	SE
Location for Use	Face	Face	SE
Environment of Use	OTC	OTC	SE
Safety and EMC	IEC 60601-1 IEC 60601-1-2 IE C60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IE C60601-1-11 IEC 60601-2-57	SE
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	SE

8. Conclusion:

The proposed device utilizes the same technological characteristics as the above listed model configurations of K202390, and is also for use in the treatment of mild to moderate acne and treatment of wrinkles. After an analysis of the proposed device's design, functionality, safety, materials, and performance testing results, the sponsor believes that the device's technology does not raise new types of questions regarding safety and efficacy of the subject device for the proposed indications, and performance testing supports that the device can be used safely and effectively. The subject device Skin Care Beauty Mask (Model: MJ-06) is considered to substantially equivalent to the above-specified devices of K202390.

9. Date prepared: May 2022