December 13, 2023

Shenzhen Kaiyan Medical Equipment Co., Ltd
Alain Dijkstra
Official Correspondent
Building#3 and Building#5, 40th of Fuxin Street
Huaide Community Fuyong Town, Baoan District
Shenzhen, 518103 China

Re: K232863
Trade/Device Name: Radiant Renewal Skincare Wand (HD-15, HD-15A)
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, NFO
Dated: August 23, 2023
Received: September 15, 2023

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 (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.

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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2023.12.13 13:54:39 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232863

Device Name
Radiant Renewal Skincare Wand (HD-15, HD-15A)

Indications for Use *(Describe)*
The Radiant Renewal Skincare Wand (Model: HD-15) is intended for treating wrinkles on the face and is indicated for over-the-counter use.
The Radiant Renewal Skincare Wand (Model: HD-15A) is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use, the red light is intended for treating wrinkles on the face and is indicated for over-the-counter use.

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 K232863

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: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
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Application Correspondent:

Contact Person: Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

2. Subject Device Information:

Trade Name: Radiant Renewal Skincare Wand, model: HD-15, HD-15A
Classification Name: Light based OTC for winkle reduction; Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Review Panel: General & Plastic Surgery
Product Code: OHS, NFO
Regulation Number:21 CFR 878.4810, 21 CFR 882.5890
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K171821)

Sponsor: Heat In A Click
Trade Name: 2 Face / Face Evolution (Model: 2 Face / Face Evolution)
Classification Name: Stimulator, Transcutaneous Electrical, Aesthetic Purposes; Light Based Over the Counter Wrinkle Reduction, over-the counter powered light based laser for acne
Review Panel: General & Plastic Surgery
Product Code: NFO, OHS, OLP
Regulation Number: 21 CFR 882.5890, 21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K212342)

Sponsor: ZIIP, Inc.
Trade Name: ZIIP+ Device

Classification Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief.
Review Panel: Neurology
Product Code: NFO
Regulation Number: 21 CFR 882.5890
Regulation Class: II

Predicate Device 3 (K163470)
Sponsor: ShenZhen Siken 3D Technology Development Co.,Ltd.
Trade Name: Galvanic Spa
Classification Name: stimulator, transcutaneous electrical, aesthetic purposes
Review Panel: Neurology
Product Code: NFO
Regulation Number: 21 CFR 882.5890
Regulation Class: II

Predicate Device 4 (K202055)
Sponsor: Heat In A Click LLC
Trade Name: Looper (Model: ZX-579S)
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over The Counter Wrinkle Reduction (OHS)
Review Panel: General & Plastic Surgery
Product Code: OLP, OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

The Radiant Renewal Skincare Wand (Model: HD-15, HD-15A) is a hand-held, battery-powered device used to stimulate the face and neck superficially through application of transcutaneous electrical currents and treat wrinkles by emitting 630 nanometers of red light. The device is powered by a Lithium-Ion rechargeable battery, and it has a charging cable, carrying case and instruction manual.
There are two models of the device, with only differences in operating modes. Model HD-15 only has a red-light wrinkle treatment effect, while Model HD-15A has two functional modes: one is red light wrinkle treatment, and the other is micro current stimulation of the face and neck.
Both of them have one button to turn on/off the device. For model HD-15A, this button also can switch the mode.
The device will automatically shut down after 12 minutes of operation. The recommended treatment time is 3 minutes. After every three minutes of treatment, the device will vibrate to indicate the time. If you need to continue treatment, simply turn on the device again.

5. Intended Use / Indications for Use

The Radiant Renewal Skincare Wand (Model: HD-15) is intended for treating wrinkles on the face and is indicated for over-the-counter use.
The Radiant Renewal Skincare Wand (Model: HD-15A) is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use, the red light is intended for treating wrinkles on the face and is indicated for over-the-counter use.

6. Comparison to predicate devices

Compare with the 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 the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Heat In A Click	ZIIP Inc.	ShenZhen Siken 3D Technology Development Co., Ltd.	Heat In A Click LLC	--
510 (K) Number	K232863	K171821	K212342	K163470	K202055	--
Device Name	Radiant Renewal Skincare Wand	2 Face / Face Evolution (Model: 2 Face / Face Evolution)	Micro-current Wrinkle Reduction Facial Service	Galvanic Spa, Model: SKB-1405	Looper	--
OTC/Rx	OTC	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	NFO, OHS	NFO, OHS, OLP	NFO	NFO	OHS, OLP	Same
Mechanism of Action	Microcurrent electrical therapy to deliver skin stimulation; Red light treatment for facial wrinkles.	Microcurrent electrical therapy to deliver skin stimulation; Red light treatment for facial wrinkles; Bule light treatment for mild to moderate inflammatory acne.	Microcurrent electrical therapy to deliver skin stimulation	Microcurrent electrical therapy to deliver skin stimulation	Blue light therapy for mild to moderate inflammatory acne; Red light treatment for facial wrinkles.	Same
Regulation Number	21 CFR 882.5890, 21 CFR 878.4810	21 CFR 882.5890, 21 CFR 878.4810	21 CFR 882.5890	21 CFR 882.5890	21 CFR 878.4810	Same
Indications for Use / Intended use	The Radiant Renewal Skincare Wand (Model: HD-15) is intended for treating wrinkles on the face and	2 Face / Face Evolution is a hand-held device for over-the counter aesthetic purposes. (1) The EMS mode is indicated for	The ZIIP+ Device is intended for facial and neck stimulation and is indicated for over-the-counter use.	The Galvanic Spa (Model: SKB-1405) is intended for facial stimulation and is indicated for over-the counter cosmetic use. The anatomical site for application of	Looper (Model: ZX-579S) is a hand-held device for over-the counter aesthetic purposes. The Photon mode red light is indicated for the use in treating wrinkles on the face, and	Same

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
	is indicated for over-the-counter use. The Radiant Renewal Skincare Wand (Model: HD-15A) is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use, the red light is intended for treating wrinkles on the face and is indicated for over-the-counter use.	facial stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.		the Galvanic Spa is the face.	the blue light is indicated for the treatment of the mild to moderate inflammatory acne.	
Material/ Biocompatibility	PC and Aluminum	ABS Plastic & Stainless Steel	Biocompatible materials typically used in medical devices and identical to predicate ZIIP device	Stainless steel	ABS Plastic & Stainless Steel	Different, note 1
Power Source	Lithium battery: 3.7V, 500mAh, 1.85Wh	DC 3.7V 2200mAh	Internal Rechargeable Lithium Ion Battery	3.7V Li-battery	DC 3.7V 1000mA Li battery	Different, note 2
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Same
Human Factors	Hand-held device	Hand-held device	Hand-held device	Hand-held device	Hand-held device	Same
Electrical Safety	Compliant with IEC	Compliant with IEC	Compliant with IEC 60601- 1,	Compliant with IEC 60601- 1,	Compliant with IEC 60601- 1,	Same

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
	60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 62471, IEC 60601-2-10, IEC 60601-2-57	60601- 1, IEC 60601-1-2, IEC 62471, IEC 60601-2-57	IEC 60601-1-2, IEC 60601-1-11	IEC 60601-1-2, IEC 60601-2-10	60601-1-2, 60601-1-11, 62471, IEC 60601-2-57	
Type of Energy	LED, Electrical current	LED, Electrical current	Electrical current	Electrical current	LED	Same
Charging Method	External wall adaptor	External wall adaptor	External wall adaptor	External wall adaptor	No publicity	Same
Detailed Output Characteristics						
Power Source(s)	--	--	--	--	--	--
a) Method of Line Current Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	One rechargeable Lithium-Ion Battery and External Charger Isolation	Type BF	Same
b) Patient Leakage Current	--	--	External Charger Included	--	No publicity	--
- Normal Condition	≤100μA	No publicity	46 μA	No publicity	No publicity	Different, note 2
- Fault Condition	≤500μA	No publicity	46 μA		No publicity	Different, note 2
Number of Output Modules	1	2	1	1	Not applicable	Same
Number of Output Channels	1	2	1	1	Not applicable	Same
a) Synchronous or Alternating	N/A – 1 Output Channel	No publicity	N/A – 1 Output Channel	Alternating	Not applicable	Same
b) Method of Channel Isolation	N/A – 1 Output Channel	Type BF	N/A – 1 Output Channel	No publicity	Not applicable	Same
Regulated Current or Regulated Voltage	Both	Both	Both	Both	Not applicable	Same
Software/	Yes	Yes	Yes	Yes	Yes	Same

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
Firmware/ Microprocessor Controlled						
Automatic Overload Trip	Yes	No	Not required because of circuit design (Current and Voltage Limited by Circuit Design and Firmware)	Yes	Not applicable	Same
Automatic No-Load Trip	No	Yes	Yes (Reversion to Fixed Voltage Output)	Yes	Not applicable	Different, note 2
Automatic Shut Off	Yes	Yes	Yes	Yes	Yes	Same
Patient Override Control	Yes	Yes	Yes	Yes	Yes	Same
Indicator Display						
a) On/Off Status	Yes	Yes	Yes (LED Illumination on Conduction)	Yes	Yes	Same
b) Low Battery	Yes	Yes	Yes	No	Yes	Same
c) Voltage/Current Level	Yes	Yes	Yes (LED Illumination on Target Current Levels)	Yes	Yes	Same
Output Specifications						
Waveform	Pulsed Biphasic	Pulsed Biphasic, Modulated Square	Pulsed Biphasic	Pulsed Biphasic	Not applicable	Same
Shape	Rectangular	Rectangular	Modulated Square Wave	Symmetric biphasic, rectangular	Not applicable	Same
Maximum Output Voltage	164 mV @ 500Ω 540 mV @ 2kΩ 2.28V@ 10kΩ	310mV @ 500Ω 1.16V @ 2kΩ 5.56V @ 10kΩ	154 mV @ 500Ω 465 mV @ 2kΩ 2.2 V @ 10kΩ	156mV @ 500Ω 0.78V @ 2kΩ 2.6V @ 10kΩ	Not applicable	Similar, note 3
Maximum Current Density	328 µA @ 500Ω 270 µA @ 2kΩ	620µA @ 500Ω 580µA @ 2kΩ 556µA @	309 µA @ 500Ω 232 µA @ 2kΩ 202 µA @	0.31mA @ 500Ω 0.39mA @ 2kΩ 0.26mA @ 10kΩ	Not applicable	Similar, note 3

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
	228 μA @ 10kΩ	10kΩ	10kΩ			
Frequency range	10.5Hz	8.333Hz	No publicity	9.09 Hz±10 %	Not applicable	Similar, note 3
Pulse duration	48ms±10%	60ms	No publicity	55 ms	Not applicable	Similar, note 3
Maximum Phase Charge	15.74 μC@ 500Ω	26.31μC @ 500Ω	6.16 μC@ 500Ω	17.1 μC @ 500Ω	Not applicable	Similar, note 3
Maximum Current Density	0.10 mA/cm²@ 500Ω	0.330mA/cm² @500Ω	0.34 mA/cm²@ 500Ω	0.274mA/cm²@500Ω (The Electrode Size: 1.13 cm²)	Not applicable	Similar, note 3
Maximum Power Density	0.004 mW/cm²@ 500Ω	4.34μW/cm² @500Ω	3.44 W/ cm²@ 500Ω	42.5μW/cm²@500Ω (The Electrode Size:1.13cm²)	Not applicable	Similar, note 3
ON time	Constant	Constant	Constant	Adjustable, due to different levels	Not applicable	Same
OFF time	None	None	None	Adjustable, due to different levels	Not applicable	Same
Burst Mode (i.e. pulse trains)	N/A – no burst mode	No publicity	N/A – no burst mode	No publicity	Not applicable	Same
LED output Specification						
LED wavelength	Red: 630nm ± 10nm	Red: 630 ± 3nm, Blue: 415 ± 3nm	Not applicable	Not applicable	Red: 630 ± 10nm, Blue: 415 ± 10nm	Same
Irradiances	55mW/cm² ± 10%	Red light: 73.26mw/cm² ± 10% Blue: 64.10mw/cm² ± 10%	Not applicable	Not applicable	Red light: 55mw/cm² ± 10% Blue: 20-65mw/cm²	Similar, note 4
LED output Specification						
Environment for operating	Temperature: 0-30℃ Humidity: 30-95% Atmospheric Pressure: 700hPa-1060hPa	No publicity	Temperature: 5 ~ 40° C	Temperature: 5°C~40°C Humidity: ≤80 %	Temperature: 0-30℃ Humidity: 30-95% Atmospheric Pressure: 700hPa-1060hPa	Different, note 2
Environment for storage	Temperature: -5-55℃ Humidity:	No publicity	Temperature: -25 ~70° C Humidity: 10	Temperature:0~45°C Humidity: ≤	Temperature: -5-55℃	Different, note 2

Elements of Comparison	Subject device	Predicate device 1 (K171821)	Predicate device 2 (K212342)	Predicate device 3 (K163470)	Predicate device 4 (K202055)	Remark
	20-95% Atmospheric Pressure: 700hPa-1060hPa		~90% RH	≤93%	Humidity: 20-95% Atmospheric Pressure: 700hPa-1060hPa	

Comparison in Detail(s):

Note 1:

Although the "Material/Biocompatibility" is different from the predicate devices, both have the same contact category and duration, and all of them complied with the ISO 10993 series standards' requirements. So, these differences will not raise any safety or effectiveness issues.

Note 2:

Although the "Power Source", "Patient Leakage Current under", "Normal Condition" and "Fault Condition", "Automatic No-Load Trip", "Environment for operating" and "Environment for storage" are a little different from the predicate devices, they all complied with the IEC 60601-1, IEC 60601-1-2 and IEC 62133-2 safety standards' requirements. So, these differences will not raise any safety or effectiveness issues.

Note 3:

Although the "Maximum Output Voltage", "Maximum Current Density", "Frequency range" "Pulse duration", "Maximum Phase Charge", "Maximum Current Density" and "Maximum Power Density" of subject device are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 safety standards' requirements, So, these differences will not raise any safety or effectiveness issues.

Note 4:

Although the "Irradiances" of subject device is a little different from the predicate devices, the values are similar and there are many similar devices market with the same treatment wavelength and Irradiance for the same intended purpose. Besides, both of the subject device and predicate device comply with IEC 60601-1, IEC 60601-2-57 safety standards' requirements, So, these differences will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device for validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment --Part 1: 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 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems.
- IEC 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

2) Biocompatibility Test

The component of the Radiant Renewal Skincare Wand (Models: HD-15, HD-15A) has been conformed to ISO 10993-5, ISO 10993-10 and ISO 10993-23.

3) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation

Usability testing was conducted on the Radiant Renewal Skincare Wand (Models: HD-15, HD-15A), which complies with IEC 62366-1 and IEC 60601-1-6.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: December 13, 2023

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K171821, K212342, K163470 and K202055.