September 28, 2023

Medical San Indústria de Equipamentos Médicos Ltda
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
2950 West Cypress Creek Rd. Ste 110
Fort Lauderdale, Florida 33309

Re: K231901
Trade/Device Name: Hakon, Hakon Smart
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: GEX
Dated: June 27, 2023
Received: June 28, 2023

Dear Rodrigo Abreu:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S 2023.09.28
17:04:54 -04'00'

Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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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)*
K231901

Device Name
Hakon and Hakon Smart

Indications for Use *(Describe)*
The Dermatological Diode Laser (Model: Hakon and Hakon Smart) are intended for the removal, permanent reduction of hair on all skin types (Fitzpatrick skin types I-VI), including tanned skin.
Permanent hair reduction is defined as the stable, longterm reduction in the number of hairs growing back when measured at 6, 9, and 12 months after completion of a treatment regimen.

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.

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Section 5
510(k) SUMMARY K231901

A) Submitter's Name: Medical San Indústria de Equipamentos Médicos Ltda.

Owner / Operator Registration Number: Not available yet.

Manufacturer Registration Number: Not available yet.

Address: Rua Alberto Muller, 1100 Block 20 - Rooms 404 and 406

Bairro Carneiros – Lajeado RS – Brazil - 95913-528

B) Phone and Fax Numbers

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C) Contact Person:

Francis Laion de Padua
Tel.: +55 (51) 3720-2762
Email: regulatorio@medicalsan.com.br

D) Preparation Date: September 27, 2023

E) Classification Name:

Common / Usual Name: Powered laser surgical instrument

Proprietary Name: Hakon and Hakon Smart

Product Code: GEX

Class: Class II

Regulation: 21 CFR 878.4810

F) Device Description

The Hakon and Hakon Smart device is a micro-controlled equipment used in diode laser therapies at wavelengths of 808nm intended to remove unwanted hair.

G) Device Operations Principles

The technique is based on the principle of selective thermal destruction, specifically targeting the germinal cells within the hair follicle. By utilizing laser light, the melanin present in the hair absorbs the energy, leading to the destruction of the hair bulbs in the anagen phase. The anagen phase represents the active growth stage of the hair follicle, characterized by highly pigmented matrix cells and a connection to the dermal papilla. It is during this phase that the treatment achieves its highest success rates.

Melanin, being the primary chromophore in hair follicles, enables the utilization of light wavelengths ranging from 600 to 1100nm for safe and effective selective photo thermolysis. These wavelengths ensure optimal targeting of the hair follicles while maintaining efficacy and safety throughout the treatment process.

H) Predicate Device:

The Hakon and Hakon Smart is equivalent with the following predicate device:

510(k) Number	Model	Company
K210663	CM01D/CM02D	Beijing HuaCheng Taike Technology Co., Ltd.

I) Substantial Equivalence Comparison

a. Indications for Use:

Indications for Use Comparison	
Hakon and Hakon Smart	**CM01D/CM02D**
The Dermatological Diode Laser (Model: Hakon and Hakon Smart) is intended for the removal, permanent reduction of hair on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent hair reduction is defined as the stable, long-term reduction in the number of hairs growing back when measured at 6, 9, and 12 months after completion of a treatment regimen.	The Dermatological Diode Laser (Model: CM01D/ CM02D) is intended for the removal, permanent reduction of hair on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent hair reduction is defined as the stable, long-term reduction in the number of hairs growing back when measured at 6, 9, and 12 months after completion of a treatment regimen.

b. Technological Characteristics Comparison:

The predicate devices used to establish substantial equivalence for the Hakon and Hakon Smart device is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Hakon and Hakon Smart to each of the predicate devices stratified by functional modality.

ITEM	PROPOSED DEVICE	PREDICATE DEVICE K210663	OBSERVATION
Device Name	Equipment Laser System for Depilation	Diode laser dermatology systems	-
Product Model	Hakon and Hakon Smart	CM01D/CM02D	-
K number	-	K210663	-
Product code	GEX	GEX	Same
Regulation classification	21 CFR 878.4810	21 CFR 878.4810	Same
Class	2	2	Same
Indication of Use	The Dermatological Diode Laser (Model: Hakon and Hakon Smart) is intended for the removal, permanent reduction of hair on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent hair reduction is defined as the stable, long-term reduction in the number of hairs growing back when measured at 6, 9, and 12 months after completion of a treatment regimen.	The Dermatological Diode Laser (Model: CM01D/ CM02D) is intended for the removal, permanent reduction of hair on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent hair reduction is defined as the stable, long-term reduction in the number of hairs growing back when measured at 6, 9, and 12 months after completion of a treatment regimen.	Same
Settings	Main Unit	Main Unit	Same
	hand piece	hand piece	Same
	control pedal	control pedal	Same
principle of operation	diode laser	diode laser	Same

Laser Type	diode laser	diode laser	Same
laser rating	Class IV	Class IV	Same
Wave-length	808nm	808nm	Same
Spot size	10x12mm	CM01D: 10 x 30 mm CM02D: 9x12mm	Similar
Fluency	1-70 J/cm2	CM01D: 5-100 J/cm² CM02D: 3-30 J/cm²	Similar
Frequency	1-10 Hz	CM01D: 1-10 Hz CM02D: 1-3 Hz	Same
Pulse Duration	10 -400 ms	CM01D: 15-400ms CM02D: 35-400ms	Similar
Power supply	110V/60Hz or 230V/50Hz	AC 110V/60Hz	Similar
Dimension	393 mm x 430 mm x 1130 mm	CM01D: 650 mm x 650 mm x 1230 mm CM02D: 252 mm x 210 mm x 193 mm	Similar
Weight	65kg	60kg	
EMC, electrical and laser safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-22	Comply with IEC 60601-2-22	Same
Direct/indirect patient contact materials and biocompatibility			
Patient **direct indirect**	Tip of the Handle (6063 Aluminum & S1 Quartz)	Tip of the Handle (6063 Aluminum & Quartz)	Same

Contact Materials			
Biocompatibility	ISO 10993-1	ISO 10993-1	Same

SE Discussion

The subject device differs from the predicate in several key aspects, including spot size, fluency range, and pulse duration.

Spot Size: The predicate device has a spot size ranging from a minimum of 9mm to a maximum of 30mm, while the subject device falls within the dimensions of 10mm to 12mm. This ensures that the subject device maintains a safe spot size within the range specified by the predicate.

Fluency Range: The predicate device has a fluency range of 3 - 100J/cm², whereas the subject device has a lower fluency range of 1 - 70J/cm². The subject device has a maximum thermal energy 30% lower than the predicate and a minimum thermal energy 76% lower.

Pulse Duration: The predicate device has a pulse duration limit of 15 - 400ms, while the subject device has a pulse duration of 10 - 400ms. The subject device's pulse duration has a minimum limit that is 30% lower than that of the predicate. Since the subject device has a lower pulse duration limit and not a higher one, it ensures safety in terms of pulse duration characteristics.

These differences highlight that the subject device is designed with specific technical specifications that prioritize safety. The spot size, fluency range, and pulse duration of the subject device align with the predicate, thereby providing a safe hair removal solution.

Furthermore, it is important to note that these differences in spot size, fluency range, and pulse duration do not compromise the efficiency or effectiveness of the subject device. Despite the adjustments made for enhanced safety, the subject device maintains its ability to deliver efficient and reliable hair removal results. The modifications in these technical specifications ensure a safe treatment experience without compromising the overall performance and efficacy of the device.

c. Non-Clinical Evaluation (Performance and Safety Evaluation):

In order to reach high performance, safety and effectiveness the device Hakon and Hakon Smart was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

Description	**Standard Number**
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22
Safety Of Laser Products - Part 1: Equipment Classification And Requirements	IEC 60825-1
Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	ISO 10993-1

d. Clinical Testing:

No clinical trial was performed.

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Hakon and Hakon Smart demonstrate safety, effectiveness and equivalent to the predicates above.