February 15, 2023

Unilam Co., Ltd.
% Edward Park
RA Director
Allura Medical Solutions Inc.
5485 Rathdrum Way
Antioch, California 94531

Re: K221523
Trade/Device Name: Tanning Lamp
Regulation Number: 21 CFR 878.4635
Regulation Name: Sunlamp Products And Ultraviolet Lamps Intended For Use In Sunlamp Products
Regulatory Class: Class II
Product Code: LEJ
Dated: May 26, 2022
Received: May 26, 2022

Dear Edward Park:

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K221523

Device Name
Tanning Lamp

Indications for Use *(Describe)*
These devices are UV-B and UV-A lamps intended to provide ultraviolet radiation to tan the skin.

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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UNILAM CO., LTD.
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Ulsan Gwangyeogsi, 689-813, Republic of Korea
Tel. 82-55-372-2509 / Fax. 82-55-372-2513

5. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:	UNILAM CO., LTD. 23 Samdong-Ro, Samnam-Myeon, Ulju-Gun, Ulsan Ulsan Gwangyeogsi, 689-813, Republic of Korea Tel. 82-55-372-2509 / Fax. 82-55-372-2513 Edward Park
Contact Person:	Allura Medical Solution Inc. 5485 Rathdrum Way, Antioch, CA 94531, USA
Date Summary Prepared:	November 16, 2022

Device Information

Trade Name(s):	Tanning Lamp
Classification Name:	Ultraviolet lamp for tanning
Panel:	General & plastic surgery
Product Code:	LEJ

Predicate Device

< Predicate device >

- Ultraviolet Sun Tanning Lamp (G.L.E. Gesellschaft für lichttechnische Erzeugnisse mbH K151674)

Device Description

The Unilam Tanning lamps are high-pressure metal-halide lamps, each comprised of a quartz glass bulb filled with metal halide, mercury, and argon gas, and equipped with 2 electrodes and an electrical connector, to provide ultraviolet light in order to tan the human body.

Indications for Use

These devices are UV-B and UV-A lamps intended to provide ultraviolet radiation to tan the skin.

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Summary of the technological characteristics compared to the predicate device

Features	New Device	Predicate Device
Manufacturer	UNILAM CO., LTD.	G.L.E. Gesellschaft für lichttechnische Erzeugnisse mbH
Product Name	Unilam Tanning Lamp	Ultraviolet Sun Tanning Lamp
510k Number	K221523	K151674
Establishment Registration	3007123863	3002553648
Product Code	LEJ	LEJ
Regulation Number	21 CFR 878.4635	21 CFR 878.4635
Device Classification Name	Ultraviolet Lamp for Tanning	Ultraviolet Lamp for Tanning
Class	II	II
Device Model	Various	Various
Indications for Use	These devices are UV-A and UV-B lamps intended to provide ultraviolet radiation to tan the skin.	These devices are UV-A and UV-B lamps intended to provide ultraviolet radiation to tan the skin.
Sterilization	Not applicable	Not applicable
Technical Characteristic	Radiate UVA (315-400nm) and UVB (280-315nm). UVC is cut by the quartz bulb.	Radiate UVA (315-400nm) and UVB (280-315nm). UVC is cut by the quartz bulb.
Frequency	60 Hz	50-60 Hz
Sterilization	Not applicable	Not applicable
Biocompatibility	Not applicable	Not applicable

Non-Clinical Study performance

Performance testing was conducted comparing the Unilam Tanning Lamp and the predicate device. The subject device emits UV-B and UV-A radiation and fulfill the requirements of 21 CFR 878.4635 and the performance standard 21 CFR 1040.20. The ratio of UV-C (200~260nm) to UV-B (260~320nm) meets the requirement (<0.003) per 21 CFR 1040.20(C)(1) at any distance and direction from the product or lamp.

Clinical Study performance

Clinical testing was not needed in this 510(k) to support substantial equivalence of the subject device to the predicate device.

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Conclusion

The subject device tanning lamps use the same metal halide technology that is used in the predicate K151674 device's tanning lamps. Differences between the proposed device and predicate device do not raise new types of questions regarding safety and effectiveness, and performance testing supports that the proposed device can be used safely and effectively for the proposed indications for use. The K221523 device is considered to be substantially equivalent to the predicate K151674.