DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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G.I.E.- Gesellschaft Fur Lichttechnische Erzeugnisse Mbh
% Oliver Eikenberg, Ph.D.
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October 20, 2015

Re: K151674
Trade/Device Name: Ultraviolet Sun 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: June 19, 2015
Received: June 22, 2015

Dear Dr. Eikenberg:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151674

Device Name
Ultraviolet Sun Tanning Lamp

Indications for Use *(Describe)*
These devices are UV-B and UV-A lamps intended to provide ultravrolet 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 - 510(k) Summary
per 21 CFR 807.92

1. Submission Sponsor

NAME	G.L.E. Gesellschaft für lichttechnische Erzeugnisse mbH
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2. Submission Correspondent

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3. Date Prepared

Septmeber 14, 2015

4. Device Identification

Trade/Proprietary Name:	***Ultraviolet Sun Tanning Lamp***
Common/Usual Name:	Ultraviolet lamp for tanning
Classification Name:	Ultraviolet lamp for tanning
Classification Regulation:	21 CFR 878.4635
Product Code:	LEJ
Device Class:	Class II
Review Panel:	General & Plastic Surgery
Guidance:	Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (FORM FDA 3630 (10/14), 21 CFR 1002)

5. Legally marketed Predicate Devices

Tanning lamps (K143043, 04/02/2015) from Unilam Co., Ltd. (Onbix Corp.), South Korea

6. Device Description

These UV Tanning lamps are medium pressure halide lamps with a quartz glass bulb, filled with metal halide, mercury and argon gas, equipped with 2 electrodes and a socket to provide ultraviolet radiation to induce skin tanning at any part of the living human body.

7. Indications for use/ Intended Use

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

8. Comparison of Technological Characteristics

The following table compares the UV Tanning lamp devices to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1 – Comparison of Characteristics for *UV Tanning Lamp* from G.L.E. versus Unilam

	Proposed Device	Predicate Device	Similarities/Differences
Product Name:	Ultraviolet Sun Tanning Lamp	Unilam Tanning Lamp	-
510(k):	Pending	K143043	-
Establishment Registration	3002553648	3007123863	-
Product Code:	LEJ	LEJ	Same
Regulation Number :	21 CFR 878.4635	21 CFR 878.4635	Same
Device Classification name	Ultraviolet lamp for tanning	Ultraviolet lamp for tanning	Same
Class:	II	II	Same
Device model	Various	Various	Same
Intended Use:	Intended to provide ultraviolet radiation to tan the skin.	Intended to provide ultraviolet light to tan the skin.	Same
Body Location:	skin tanning at any part of the living human body	skin tanning at any part of the living human body	Same
Technological Characteristic:	Radiate UVA (320-400nm) and UVB (260-320nm), UVC is cut by the quartz bulb.	Radiate UVA (315-400nm) and UVB (280-315 nm) UVC is cut by the quartz bulb.	Same, just different reference definition for UV categorization used
Frequency	50-60 Hz	60 Hz	Similar
Battery Operated:	No	No	Same
Sterile:	N/A	N/A	N/A
Biocompatibility:	N/A	N/A	N/A
Electrical Compatibility & Safety Testing	N/A	N/A	N/A, electric component without electric unit

9. Non-Clinical Performance Data

These lamps emitting UV-B and UV-A radiation and fulfill the requirements of 21 CFR 878.4635 and the performance standard 21 CFR 1040.20.

Spectral characteristics, a plot of the spectral irradiance from the product in the 200-710 nm wavelength range, irradiance values per nanometer (Watt/cm²/nm) over the wavelength range of 200 to 400 nm, Irradiance ratios (<0.003) as required per 21 CFR 1040.20(c)(1), quality control and life & reliability testings are reported for each single lamp model in the "product reports" as required by FDA form 3630 (10/14), "Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002)". A performance testing was conducted comparing the irradiance performance of the Ultraviolet Sun tanning Lamp from G.L.E. to the predicate Unilam tanning lamp.

The Ultraviolet Sun Tanning Lamp devices passed all the testing in accordance with national and international standards. All tanning units were tested and manufactured according to

- EN 60335-2-27 "Safety of household and similar electrical appliances. Part 2: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation."
- Device Risk Analysis per ISO 14971

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device and the described tanning lamps are only a lamp component, which should be used only in combination with sunlamp products (e.g. tanning beds) equipped with an appropriate filter, to provide a source of ultraviolet tanning. In addition these types of devices, including the predicate devices, have been on the market for many years without changes in technical specifications with a proven safety and efficiency for the use of the devices. The non-clinical testing and device characteristics detailed in this submission support the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the Ultraviolet Sun tanning lamps (G.L.E.) and the predicate tanning lamp devices (Unilam) do not raise any questions regarding its safety and effectiveness. Technological product characteristics, performance testing and compliance with voluntary standards, demonstrate that the Ultraviolet Sun tanning lamp devices are substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, performance characteristics, and intended use.

The Ultraviolet Sun tanning lamp devices, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate device from Unilam.