DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 2, 2015

Unilam Company, Ltd
Ho Dong, Yang
Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul, 135-768, South Korea

Re: K143043
Trade/Device Name: Tanning Lamp
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet lamp for tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: February 11, 2015
Received: February 25, 2015

Dear Mr. Yang:

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" (21CFR 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,

Jennifer R. Stevenson -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)*
K143043

Device Name
Tanning Lamp

Indications for Use *(Describe)*
Intended to provide ultraviolet light 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.

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Date Summary Prepared: **Apr 02, 2015**

Device Information:

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

Predicate Device Information:
NARVA LICHTQUELLEN GMBH + CO KG (Registration number: 3003994709)

Device Description:
Tanning lamp is electronic products to be intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths to induce skin tanning.

Intended Use:
Intended to provide ultraviolet light to tan the skin

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of the technological characteristics compared to the predicate device
new device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below

Comparison table is as follows

Features	New device	Predicate device
manufacturer	Unilam Co., Ltd.	NARVA LICHTQUELLEN GMBH + CO KG
Registration number	3007123863	3003994709
Product code	LEJ	LEJ
Product name	**Unilam Tanning Lamp**	**Cosmedico Light Inc.**
Intended use	Intended to provide ultraviolet light to tan the skin	Intended to provide ultraviolet light to tan the skin
sterilization	Not applicable	Not applicable
Power source	Ballast Cosmedico #74427 (input 220V/60Hz)	Ballast Cosmedico #74427 (input 220V/60Hz)
Technical characteristic	Radiate UVA(315~400nm) and UVB(280~315nm) The UVC is cut by the quartz bulb.	Radiate UVA(315~400nm) and UVB(280~315nm) The UVC is cut by the quartz bulb.
frequency	60Hz	60Hz
Device model	various	various

Non-Clinical Study performance
Performance studies were conducted comparing the Unilam UV lamps to the predicate Cosmedico UV lamps. These studies included electrical power requirements for lamp activation, lamp spectral output and lamp energy output. Specifically the company prepared individual test data sheets that include an illustration of the output spectra of the bulbs in nm increments, the energy output for each bulb in the UVA and UVB range, the approximate lifetime of the bulbs, a description of the individual bulb dimensions and an illustration of the unique connector design for the individual bulbs. This information was prepared to the Unilam bulbs and the Cosmedico predicate bulbs. Tables were provided comparing the wavelength range and UVA and UVB output energies for Unilam compared to Cosmedico.

Conclusion
Based on the information provided in this summary we conclude that Unilam Tanning Lamp is safe and effective and substantially equivalent to the NARVA LICHTQUELLEN GMBH + CO KG