DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 1, 2016

IBL Acquisitions LLC
% Greg Bender
Managing Member
Bender & Bender Project Management Services LLC
3678 Gould Dr
Carmel, Indiana 46033

Re: K152405
Trade/Device Name: IBL 5000 Tanning Booth
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: July 11, 2016
Received: July 15, 2016

Dear Greg Bender:

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 Part 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,

Christopher J. Ronk -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)*
K152405

Device Name
IBL 5000 Tanning Booth

Indications for Use *(Describe)*
The device is intended to be used for the tanning of Human 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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510(k) Summary
As required by 21 CFR 807.92(c)

Device Name	IBL 5000	
Submitters name/contact details	IBL Acquisitions Inc. 2653 Tobey Drive Indianapolis, IN 46219 Contact Details: Michael Gilley President Tel: 317-217-1700 Fax: 317-890-0103	
Summary Preparation Date	31st July 2015	
Device Name & Classification	Trade Name: Common Name: Classification Name: Device Classification: Product Code:	IBL 5000 (200W) and IBL 5000 (160W) Tanning Booth Ultraviolet lamp for tanning Class II, 21 CFR 878.4635 LEJ
Intended Use:	The device is intended to be used for the tanning of human skin.	
Device Description:	The IBL 5000 tanning booth is available in two configurations, a 200W configuration that utilizes 79 inch fluorescent UV lamps and a 160W configuration that utilizes 71 inch fluorescent UV lamps. Each configuration consists of a metal structure with 50 lamps vertically arranged in a manner that surrounds the tanner so as to provide a consistent all around tan. The user stands in the center of the booth. Double doors allow entry and exit from the booth. The lamps are powered by inductive (choke) type ballasts. The duration of exposure is controlled by a user settable electronic timer. The session time can be set to any value called for on the recommended exposure schedule. Session time cannot be set longer than the maximum recommended exposure schedule time. A backup timer is provided that ensures the booth's lamps cannot operate longer than the maximum recommended exposure. A stop switch is provided within the tanning area to immediately turn off the UV lamps if needed. The dosage of UV irradiation is within allowable limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21st 1986 titled Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products.	
Predicate Devices	IBL Acquisitions Inc. Model IBL 5000 8/08/2013 Per Federal Register Vol. 79, No 105 Monday, June 2, 2014 Page 31212 Section IV Premarket Notification. (Docket No. FDA-2013-N-0461) "any 510(k)-exempt sunlamp product or UV lamp intended for sale on or	

	before September 2, 2014, can serve as predicates for substantial equivalence purposes." Therefore, the IBL5000 will serve as its own predicate as it was on the market prior to September 2, 2014. The Initial Product Report for the IBL 5000 was given accession reference number 1310561-000.
Comparison of Characteristics	The IBL 5000 (200W) is identical to its predicate version on the market prior to September 2, 2014. The IBL 5000 (160W) has the following differences. - Utilizes 71 inch UV lamps instead of 79 inch lamps - Utilizes 160W ballasts instead of 200W ballasts - Utilizes staggered vertical spacing of its lamps to achieve tanning across the full body length. UV Irradiance testing was performed on both configurations to establish the exposure schedule per FDA Guidelines as well as to demonstrate substantial equivalence between the IBL 5000 (160W) and the IBL 5000 (200W) units. (refer to performance testing below) The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing device. The testing raised no new issues of safety or effectiveness and as such the IBL 5000 (200W) and IBL 5000 (160W) are considered substantially equivalent to the IBL 5000 (200W) predicate device. Labeling, Device labeling and user manual contraindications and warnings for both configurations are in compliance with the requirements of 21 CFR 1040.20 and have been updated to comply with the recently updated regulation 21 CFR 878.4635. See *Proposed Labeling* section of this submittal.
Performance Testing (non-Clinical)	Results of the UV irradiance testing performed on both configurations confirm that the dosage is within allowable limits set by the FDA performance standard 21 CFR 1040.20 and FDA Guidance letter dated August 21st 1986 titled Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products. The following additional factors were tested and/or evaluated. - Timer Software Validation and Verification - Biocompatibility of surfaces in contact with the tanner. - Electromagnetic compatibility and electrical safety. - Temperature of contact surfaces and temperature of air within tanning booth during operation. The results from these performance evaluations demonstrated the IBL 5000 (200W) and IBL5000 (160W) tanning booths met the acceptance criteria defined in the performance standard and performed comparably to the predicate device.

Conclusions	Based on safety and performance testing, technological characteristics and the intended for use of the device, the proposed IBL 5000 models have been demonstrated to be appropriate for their intended use and are considered to be substantially equivalent to the predicate device.