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

July 29, 2016

Tanda Beauty Canada Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, Pennsylvania 19103

Re: K161849
Trade/Device Name: Bright
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: OHS
Dated: July 5, 2016
Received: July 5, 2016

Dear Janice Hogan:

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,

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 on last page

510(k) Number *(if known)*

K161849

Device Name

Bright

Indications for Use *(Describe)*

The Bright device is intended to be used for the treatment of wrinkles, rhytides and fine lines in the periorbital region.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

Tanda Beauty Canada, Inc.'s Bright Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tanda Beauty Canada, Inc. (formerly Pharos Life Corporation)
11-380 Jamieson Parkway
Cambridge, Ontario, Canada
N3C 4N4

Phone: +1 212 245 2999 X 202
Facsimile: +1-519-651-2277

Contact Person: Bobae Kim

Date Prepared: July 28, 2016

Name of Device and Name

Bright

Common or Usual Name

Light Emitting Diode Therapy Device

Classification Name

Laser surgical instrument for use in general and plastic surgery and in dermatology

Predicate Devices

Tanda Beauty Canada, Inc.'s (formerly known as Pharos Life Corporation) Tanda Max OTC (K110735)

Purpose of the Special 510(k) Notice

The Bright device is a modification to the previously cleared Tanda Max OTC (K110735) device to create a smaller version of the cleared device.

Intended Use

The Bright device is indicated for the treatment of wrinkles, rhytides and fine lines in the periorbital region.

Device Description

The Bright is an over-the-counter device that uses light emitting diodes to emit red light (660 nm) during treatment. The device includes a control unit, a treatment surface and a protective cap that fits over the treatment surface area of the device when not in use. The device controls consist of a single on/off activation button. The rechargeable battery included in the device can be charged using a USB cable that is supplied.

Technological Characteristics

The Bright device is a smaller version of its predicate device (K110725). Both the predicate device and the Bright share the same technological characteristics. Both devices are handheld rechargeable battery operated units that use light emitting diodes (LEDs) to deliver red light at 660 nm to the treatment surface. The primary features of the Bright device are identical to the predicate device, and include sensors for skin contact and skin temperature, as well as a single on/off push button that activates the device. The performance specifications, such as the total output power (mW/cm2), the treatment cycle time and the treatment regimen also remain identical between the predicate (K110735) and the Bright device. The minor change of reducing the size and dimensions of the Bright compared to the predicate does not present changes to the fundamental scientific technology and essential parameters of the originally cleared predicate device.

Performance Data

A risk analysis was performed to assess the modifications to the Bright System, and confirmed that no new risks are raised. The following non-clinical performance testing was conducted to re-validate the modified device. The same test methods and criteria used on the predicate device cleared in K110735 were followed, and include:

- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. (General)
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests. (General II (ES/EMC))
- IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes. (Software/Informatics)
- ISO 10993-1 Fourth edition 2009-10-15, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [including: technical corrigendum 1 (2010)]. (Biocompatibility)
- IEC 62471, Photobiological safety of lamps and lamp systems. (Radiology) 1.0 edition (2006)
- ISO 14971, Medical devices - Application of risk management to medical devices. (General) (2010)

In all instances, the Bright functioned as intended.

Substantial Equivalence

The Bright device has the same intended use and indications, principles of operation, and technological characteristics as the Tanda Max OTC (K110735) predicate device. The minor hardware differences implemented to create a smaller version of the device and the addition of a vibration indicator in the Bright device do not present new or different questions of safety or effectiveness. Performance data demonstrates that the Bright device is substantially equivalent to the company's Tanda Max OTC predicate device.

Conclusions

In sum, the Bright device performs the same as the predicate device, the Tanda Max OTC system (K110735). The Bright device has identical intended use/indications for use and principles of operation as the predicate device. The main safety features in the predicate device, including the skin contact sensor and temperature sensor, are also preserved in the Bright device. Furthermore, the Bright device delivers the same total output power (mW/cm2) in the same treatment duration and regimen as the predicate device and therefore, no new or different questions of safety or efficacy are raised in the modified device. The smaller size and addition of a vibration indicator to improve user experience do not raise new issues of safety or effectiveness compared to the predicate. No new hazards were identified as a result of these modifications. Verification and validation through software and performance testing, electrical safety and electromagnetic compatibility/interference testing demonstrate that the Bright device is substantially equivalent.