DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 20, 2015

ON Light Sciences Incorporated
Ms. Marcy Moore
Director of Clinical and Regulatory Affairs
131 Kelekent Lane
Cary, North Carolina 27518

Re: K150212
Trade/Device Name: DeScribe® Transparent PFD Patch
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: PKO
Dated: January 30, 2015
Received: January 30, 2015

Dear Ms. Moore:

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 on last page

510(k) Number *(if known)*

K150212

Device Name

DeScribe® Transparent PFD Patch

Indications for Use *(Describe)*

The Describe® Transparent PFD Patch is indicated for use as an accessory to laser tattoo removal procedures using a 755nm Q-Switched Alexandrite laser in Fitzpatrick Skin Type I-III patients.

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.

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510(k) SUMMARY

ON Light Science's DeScribe® Transparent PFD Patch

Submitted by:

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Contact Person:

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Date Prepared: January 30, 2015

Trade Name: DeScribe® Transparent PFD Patch

Common or Usual Name: DeScribe Patch

Classification Name: Accessory to laser surgical instrument for use in general and plastic surgery and in dermatology

Regulation: 21 C.F.R. § 878.4810

Product Code: PKO

Classification Panel: General and Plastic Surgery

Predicate Device: Thermolase Corp. Carbon black solution (K950019; K971207)

Reference Devices:

Creative Technologies, Meladine (K022807)

Palomar Q-YAG, Carbon Solution (K023967)

Intended Use / Indications for Use:

The Describe® Transparent PFD Patch is indicated for use as an accessory to laser tattoo removal procedures using a 755nm Q-Switched Alexandrite laser in Fitzpatrick Skin Type I-III patients.

Technological Characteristics

The DeScribe Patch consists of two components: a dual-layer medical-grade silicone transparent film, and an optical clearing agent (OCA). The dual-layer silicone film is composed of a thin low-friction silicone membrane and a tacky silicone polymer layer. The low-friction silicone membrane forms the upper layer of the film. The tacky silicone polymer layer (i.e., the lower layer) contacts the patient's skin during the device's use. The OCA in the Device is sterile, high-purity perfluorodecalin (PFD), an inert, non-toxic liquid.

Performance Data

Clinical and non-clinical performance testing was conducted as described below. In all instances, the DeScribe Patch functioned as intended and results observed were as expected.

Design verification testing

Design verification testing verified the DeScribe Patch's product dimensions, as well as adhesion and chemical stability under dermatological laser exposure of both the optical clearing agent and silicone substrate.

Transit test: Conditioning and Package Performance

Transit testing was conducted to validate the ability of the package systems to protect the DeScribe Patch units from hazards typically associated with the shipping and distribution environment.

Two-year stability test

Two-year stability testing was successfully conducted. Packaging integrity was confirmed by 2-year accelerated aging testing accordance to ISO 11607.

Biocompatibility testing

Biocompatibility tests, as listed below, were conducted in accordance with ISO 10993-1. The results of those tests confirm that all patient-contact components of the device are biocompatible through compliance to the ISO 10993 standard series.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Systemic toxicity (acute)
- Material Mediated Pyrogen Test

Human factors validation test

Human factors validation testing demonstrated that the intended users of the subject medical device can safely and effectively perform critical tasks for the intended uses in expected use environments. This validation test of the DeScribe Patch used representative device users in a simulated use environment of appropriate realism, and addressed all aspects of intended use.

Clinical Investigation

A prospective, randomized, single-site clinical study was conducted to investigate the safety and efficacy of rapid (≤ 5 minute) multi-pass laser treatment of tattoos using the DeScribe Transparent PFD Patch. Thirty (30) subjects received one treatment session for a single tattoo using a standard Q-switched alexandrite laser. One half of the tattoo received laser treatment through the Patch, while the other control half received conventional laser treatment only. The number of passes performed on each side was recorded, as were the type and severity of any adverse effects. In all 30 subjects, the Patch side demonstrated whitening resolution within the treatment period so that an average of 3.7 passes could be made as compared to only 1.4 on the control side. Up to 4 passes were allowed during a treatment session. Mild erythema and edema were observed immediately post treatment that were fully resolved at the 1-month follow up-visit. No serious or unanticipated adverse device effects were observed in any subject.

Substantial Equivalence

The DeScribe Patch is as safe and effective as the Thermolase carbon black laser accessory device. The DeScribe Patch has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device(s). The minor technological differences between the DeScribe Patch and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the DeScribe Patch is as safe and effective as the cleared Thermolase carbon black accessory. Thus, the DeScribe Patch is substantially equivalent**.**

Conclusions

The DeScribe Patch is as safe and effective as the predicate device. Performance testing as described above has been conducted to support these claims.