



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

February 25, 2016

C.I.S. Ltd.
Mr. Ilan Sharon
4 Ben Gurion St.
Nes Ziona 7403201, Israel

Re: K152736

Trade/Device Name: Skin Care

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: GEX

Dated: February 7, 2016

Received: February 11, 2016

Dear Mr. Sharon:

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 Parts 801 and 809); 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

Indications for Use

510(k) Number (if known)

K152736

Device Name

Skin care

Indications for Use (Describe)

The Skin Care system is intended for aesthetic and cosmetic applications and for selective treatments required by medical dermatology specialties.

The skin care system and optional Hand pieces with 420 - 1050 nm wavelengths, with and without contact cooling, is indicated for, but not limited to:

- * Hair removal and Permanent Hair Reduction in all skin types (I-VI) to the Fitzpatrick scale
- Recommended wavelengths in the range of 670-1050 nm, 755-950 nm or 580-1050 nm
- * Treatment of Pigmented and Vascular Lesions in all skin types (I-VI) to the Fitzpatrick scale
- Recommended wavelength in the range of 515-950 nm
- * Treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale
- Recommended wavelength in the range of 420-950 nm
- * Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale
- Recommended wavelength in the range of 560-950 nm

Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

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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