



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 12, 2016

Active Optical Systems, Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K153718

Trade/Device Name: Spirit Hair Removal Laser Family
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: January 18, 2016
Received: February 2, 2016

Dear Mr. Job:

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 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)

K153718

Device Name

Spirit Hair Removal laser Family.

Trade / Proprietary Device Name: Spirit - 916, Spirit - 918, cFactor- 916, cFactor- 918, mFactor- 916, mFactor- 918

Indications for Use (Describe)

The Spirit Hair Removal laser Family is generally intended for dermatological use. The devices are specifically indicated for hair removal, permanent hair reduction by using selective laser energy.

The Spirit Hair Removal laser Family is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent reduction in hair regrowth is defined as the longterm, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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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Section 005 - 510(k) Summary of Safety and Effectiveness
(In accordance to 21 CFR 807.87(h))

Date of preparation: 18/01/16

Device Name

Device Name: Spirit Hair Removal laser Family.
Trade / Proprietary Device Name: Spirit - 916, Spirit - 918
cFactor – 916, cFactor - 918
mFactor – 916, mFactor - 918

Establishment Name and Registration Number of Submitter

Submitter Name: Active Optical Systems Ltd.
510(k) Owner: Active Optical Systems Ltd.
Registration Number: 3005180774
Contact person: Gil Bidas
Address: 11 Shoham St. Petach Tikva, Israel
Tel: +972-3-9236610 **Fax:** +972-3-9236620

Device Classification

Product Code: GEX
Regulation Number: 878.4810
Common Name: Spirit Hair Removal laser Family
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology. (21 CFR 878.4810)
Regulatory class: Class II
Panel 79 General and Plastic Surgery

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices

Modified Diode Laser with SHR Treatment Mode for use with the Family of Soprano XL K112031

Device Description

The Spirit Hair Removal laser Family has two models of the same device (916, & 918) and several trade names. The devices apply photothermal energy to human skin tissue to effect a desired change in the structure of the tissue. The energy is transmitted from a 810nm laser diode to the target tissue by a Treatment Handpiece that is in contact with the skin.

The 918 and 916 models have fully identical HW. The difference in the optical output power (6 -90J/cm² for the 918 model and 4.5 to 10J/cm² for the 916 model) is preset.

For the hair removal treatment, the devices utilized laser energy at the spectrum of 810nm (IR) which is absorbed by the Melanin which is located in the hair follicles. Once the energy is absorbed, it is turned into heat. The heat coagulates the hair follicles and removes the unwanted hair.

The Spirit Hair Removal laser Family was designed to comply with international standards and is constructed from metal, plastic a diode laser and other electronic components.

Indications for use

The Spirit Hair Removal laser Family is generally intended for dermatological use. The devices are specifically indicated for hair removal, permanent hair reduction by using selective laser energy.

The Spirit Hair Removal laser Family is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

Permanent reduction in hair regrowth is defined as the longterm, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Rationale for Substantial Equivalence

The Spirit Hair Removal laser Family shares the same indications for use, energy source and technological characteristics with the predicated device mentioned above (K112031) – therefore it is substantially equivalent to the predicated device.

The following table (table1) will summarize the main technological characteristics of the Spirit Hair Removal laser Family and the predicated device:

No.	Subject	916 Data	Soprano XL-SHR mode	918 Data	Soprano XL-LHR mode
1	Manufacturer	Active	Alma lasers	Active	Alma lasers
2	intended use	indicated for hair removal, permanent hair reduction			
3	severity and stage of the clinical condition	For all hair densities			
4	site of application	Hairy Skin	Hairy Skin	Hairy Skin	Hairy Skin

No.	Subject	916 Data	Soprano XL-SHR mode	918 Data	Soprano XL-LHR mode
5	patient population	Fitzpatrick I-VI	Fitzpatrick I-VI	Fitzpatrick I-VI	Fitzpatrick I-VI
6	energy intensity	4.5-10 J/cm ²	5-10 J/cm ²	6-90 J/cm ²	1-120 J/cm ²
7	Spectrum	810nm	810nm	810nm	810nm
8	Pulse train duration	11-38ms	Up to 20ms	Up to 310ms	Up to 200ms
9	Pulse repetition rate	≤10Hz	≤10Hz	≤10Hz	≤3Hz
10	Treatment area size	12*16mm	10*12mm	12*16mm	10*12mm
11	conditions of use	Used on Healthy skin	Used on Healthy skin	Used on Healthy skin	Used on Healthy skin
12	biocompatibility of materials	Complies	Complies	Complies	Complies
13	FDA approval No.		k112031		k112031

Table 1 – device substantial main points equivalence comparison

Safety & Effectiveness

The device has been designed, verified and validated complying to 21CFR 820.30 regulations. Bench and clinical data demonstrate that the Spirit Hair Removal laser Family meet the required specifications. No adverse affects have been detected.

High level summary of the tests that were used to demonstrate substantial equivalence

In order to compare the Spirit Hair Removal laser Family with the predicated device various tests were used.

The first tests were the ones that compared the intended usage and patient population.

Once it was clear that both devices are intended for the same usage and same patient population it was checked if the method of operation is equivalent.

In order to verify the data regarding the Spirit Hair Removal laser Family's method of operation, the spirit was checked under IEC 60825-1 and IEC 60601-2-22. These tests were performed by SII. Their results are summarized in the original submission Sec. 18 and show us that both the Spirit Hair Removal laser Family and the predicated device share an equivalent method of operation in terms of wavelength used, energy used, accuracy and other technological characteristics.

Once it was established that both devices share the same intended usage and method of operation a safety comparison was made by applying ISO14971 requirements on the

Spirit Hair Removal laser Family. In addition the applied part was tested under ISO10993 for biocompatibility and proved to be suitable.

After these tests, the Spirit Hair Removal laser Family underwent the testing of the safety and EMC properties so it could be compared with the predicated device.

In order to verify its safety and EMC properties, the Spirit Hair Removal laser Family was tested by SII according to IEC 60601-1 and IEC 60601-1-2. The results showed us that the Spirit Hair Removal laser Family is a safe and electrically compatible device just like the predicated device.

The combined result of all the tests led us to the opinion that the Spirit Hair Removal laser Family is substantially equivalent to the predicated device.

Guidance documents referenced\ used for the testing

No.	Test	Guidance Document
1.	Risk Analysis	ISO 14971:2007, 2012
2.	Biocompatibility	ISO 10993-1:2003
3.	Safety	IEC60601-1:2007
4.	EMC	IEC 60601-1-2:2007
5.	Safety & performance	IEC 60601-2-22:2007, IEC 60825-1:2007
6.	Substantial Equivalence	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” Dated: July 28, 2014

Table 2 – Tests and guidance documents

FDA recognized consensus standards used upon testing

No.	recognized consensus standard	Connotation
19-4	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007): Part 1 - Medical Electrical Equipment Part 1:General requirements for basic safety and essential performance US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010	Safety test comparison
037	IEC 60601-1-2: Third Edition (2007): Medical electrical equipment Part 1-2: Collateral Standard: Electromagnetic compatibility-Requirements and tests.	EMC test comparison
12-273	60825-1: 2007 (2nd Edition): Safety of laser products Part 1: Equipment classification and requirements	Safety & performance test comparison
12-208	IEC 60601-2-22: 2007 (Third Edition): Medical electrical equipment, Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment	Safety & performance test comparison

Table 3 – recognized consensus standards used

Conclusion - Substantial Equivalency

Since the predicate device and the Spirit Hair Removal laser Family share the same indications for use, substantially equivalent technological characteristics, and based on the bench tests and the assessment of clinical data, it is Active Optical Systems' opinion that the Spirit Hair Removal laser Family is substantially equivalent in terms of safety and effectiveness to the predicate device.