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.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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:

<table>
<thead>
<tr>
<th>No.</th>
<th>Subject</th>
<th>916 Data</th>
<th>Soprano XL-SHR mode</th>
<th>918 Data</th>
<th>Soprano XL-LHR mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Manufacturer</td>
<td>Active</td>
<td>Alma lasers</td>
<td>Active</td>
<td>Alma lasers</td>
</tr>
<tr>
<td>2</td>
<td>intended use</td>
<td>indicated for hair removal,</td>
<td>indicated for hair removal, permanent hair reduction</td>
<td>indicated for hair removal, permanent hair reduction</td>
<td>indicated for hair removal, permanent hair reduction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>permanent hair reduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>severity and stage of the</td>
<td>For all hair densities</td>
<td>For all hair densities</td>
<td>For all hair densities</td>
<td>For all hair densities</td>
</tr>
<tr>
<td></td>
<td>clinical condition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>site of application</td>
<td>Hairy Skin</td>
<td>Hairy Skin</td>
<td>Hairy Skin</td>
<td>Hairy Skin</td>
</tr>
</tbody>
</table>
Table 1 – device substantial main points equivalence comparison

<table>
<thead>
<tr>
<th>No.</th>
<th>Subject</th>
<th>916 Data</th>
<th>Soprano XL-SHR mode</th>
<th>918 Data</th>
<th>Soprano XL-LHR mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>patient population</td>
<td>Fitzpatrick I-VI</td>
<td>Fitzpatrick I-VI</td>
<td>Fitzpatrick I-VI</td>
<td>Fitzpatrick I-VI</td>
</tr>
<tr>
<td>6</td>
<td>energy intensity</td>
<td>4.5-10 J/cm²</td>
<td>5-10 J/cm²</td>
<td>6-90 J/cm²</td>
<td>1-120 J/cm²</td>
</tr>
<tr>
<td>7</td>
<td>Spectrum</td>
<td>810nm</td>
<td>810nm</td>
<td>810nm</td>
<td>810nm</td>
</tr>
<tr>
<td>8</td>
<td>Pulse train duration</td>
<td>11-38ms</td>
<td>Up to 20ms</td>
<td>Up to 310ms</td>
<td>Up to 200ms</td>
</tr>
<tr>
<td>9</td>
<td>Pulse repetition rate</td>
<td>≤10Hz</td>
<td>≤10Hz</td>
<td>≤10Hz</td>
<td>≤3Hz</td>
</tr>
<tr>
<td>10</td>
<td>Treatment area size</td>
<td>12*16mm</td>
<td>10*12mm</td>
<td>12*16mm</td>
<td>10*12mm</td>
</tr>
<tr>
<td>11</td>
<td>conditions of use</td>
<td>Used on Healthy skin</td>
<td>Used on Healthy skin</td>
<td>Used on Healthy skin</td>
<td>Used on Healthy skin</td>
</tr>
<tr>
<td>12</td>
<td>biocompatibility of materials</td>
<td>Complies</td>
<td>Complies</td>
<td>Complies</td>
<td>Complies</td>
</tr>
<tr>
<td>13</td>
<td>FDA approval No.</td>
<td>k112031</td>
<td></td>
<td>k112031</td>
<td></td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>No.</th>
<th>Test</th>
<th>Guidance Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Biocompatibility</td>
<td>ISO 10993-1:2003</td>
</tr>
<tr>
<td>4.</td>
<td>EMC</td>
<td>IEC 60601-1-2:2007</td>
</tr>
</tbody>
</table>

Table 2 – Tests and guidance documents

**FDA recognized consensus standards used upon testing**

<table>
<thead>
<tr>
<th>No.</th>
<th>recognized consensus standard</th>
<th>Connotation</th>
</tr>
</thead>
</table>

Table 3 – recognized consensus standards used upon testing
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.