August 1, 2018

Strata Skin Sciences, Inc.
℅ Paul Dryden
Consultant
Strata Skin Sciences, Inc. % ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K181480
  Trade/Device Name: MMD Tip
  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: June 2, 2018
  Received: June 5, 2018

Dear Paul Dryden:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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
Device Name

**MMD Tip**

Indications for Use *(Describe)*

The Multi-Micro Dose (MMD) Tip accessory is indicated for use in conjunction with the XTRAC laser system to filter the NB-UVB light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular patient.

Type of Use *(Select one or both, as applicable)*

- **XX** Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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PRASTaff@fda.hhs.gov

“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.”
5 510(k) Summary

We have prepared the 510(k) Summary according 21 CFR 807.92. This regulation has a broad definition of acceptability. We have reviewed other similar Summaries and included the applicable information and details.
Date prepared: June 2, 2018

Strata Skin Sciences, Inc.
100 Lakeside Drive, Suite 100
Horsham, PA 19044
Tel - 215-619-3200

Official Contact: Shmuel Gov – VP & General Manager

Proprietary or Trade Name: MMD Tip

Common/Usual Name: Laser surgical instrument for use in general and plastic surgery and in Dermatology

Classification Code/Name: GEX – Laser surgical instrument for use in general and plastic surgery and in dermatology
21CFR 878.4810, Class 2

Device: Multi-Micro Dose “MMD” Tip

Predicate Device: K073659 – Strata Skin Sciences – XTRAC

Device Description:
The XTRAC Ultra 2 Excimer Laser System, Model AL 10000 utilizes a hand-piece which contains tips and the subject device attaches in the same manner.

The subject device is the Multi-Micro Dose (“MMD”) Tip.

The Multi-Micro Dose (“MMD”) tip provides another method, separate of the MED mode, for determining the Optimal Therapeutic Dose (“OTD”) for each patient. The OTD is the power setting on the XTRAC Phototherapy system customized for each patient that enables the user to provide patient specific treatment doses. As an alternative to the trial and error method of the MED mode, using the MMD Tip can often determine the optimal XTRAC power setting with a single test application.

The MMD Tip filters and reduces the laser output, providing four different dose levels in a single application. The reaction of the target area to the different dose levels assists in determining the patient specific Optimal Therapeutic Dose (“OTD”).

The MMD Tip design places four (5mm x 5mm) square filters in the laser aperture. A drawing of the MMD Tip is shown below in comparison to the existing Standard Tip.

Indications for Use:
The Multi-Micro Dose (MMD) Tip accessory is indicated for use in conjunction with the XTRAC laser system to filter the NB-UVB light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular patient.

We note that the XTRAC system has the following indications:

The XTRAC Excimer Laser Phototherapy System is indicated for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB light.
**Patient Population:** Patients undergoing treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB light.

**Environment of Use:** Anywhere a patient may undergo a treatment with the XTRAC system.

**Substantial Equivalence Discussion:** Table 1 below compares the key features of the proposed device with the predicate.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Predicate K073659 XTRAC system</th>
<th>Subject Device MMD Tip for use with XTRAC system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The XTRAC Excimer Laser Phototherapy System (Model AL10000) is indicated for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB ultraviolet light.</td>
<td>The XTRAC Excimer Laser Phototherapy System (Model AL10000) is indicated for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB ultraviolet light. The Multi-Micro Dose (MMD) Tip accessory is indicated for use in conjunction with the XTRAC laser system to filter the NB-UVB light at delivery in order to calculate and individualize the maximum non-blistering dose for a particular patient.</td>
</tr>
<tr>
<td>Patient Population</td>
<td>Patients needing treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB ultraviolet light</td>
<td>Patients needing treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of targeted UVB ultraviolet light</td>
</tr>
<tr>
<td>Environment of use</td>
<td>Clinical settings</td>
<td>Clinical settings</td>
</tr>
<tr>
<td>Single Use</td>
<td>Equipment is reusable Tips are reusable</td>
<td>Tips are Single patient use, disposable</td>
</tr>
<tr>
<td>Sterile</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Mechanism of action</td>
<td>Tip directs the UVB light to the target area. Dose – 100%</td>
<td>MMD Tip provides four micro-dose outputs Dose - 94%, 60%, 45% and 30%</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Surface Contact Skin and Breached Limited duration (&lt;24 hours)</td>
<td>Surface Contact Skin and Breached Limited duration (&lt;24 hours)</td>
</tr>
<tr>
<td>Testing</td>
<td>Cytotoxicity Sensitization Irritation or Intracutaneous Reactivity Acute Systemic Toxicity Material Mediated Pyrogenicity</td>
<td>Tip Dose Accuracy and Uniformity Tip Transmission Verification Tip Shelf Life Tip Shipping</td>
</tr>
<tr>
<td>Bench testing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Indications for Use / Patient Population / Environment of Use:
As in comparison of Indications For Use above, the indications for the proposed MMD Tip is as an accessory to the predicate K073659 XTRAC system with its standard tips.

Discussion: There are no differences in proposed indications for use related to this accessory tip. It allows different dose levels to be delivered at one time for evaluation as to the dose which is non-blistering.

This difference does not raise different questions of risk or safety concerns compared to the predicate.

Prescriptive:
The devices are prescription devices.

Discussion: There are no differences.

Design and Technology:
The MMD Tip design is constructed of similar materials and components as the predicate tip. It connects to the XTRAC hand-piece in the same manner as the standard Tips of the XTRAC system.

Discussion: There are no differences in design, technology, or principle of operation which would raise different safety or effectiveness concerns compared to the predicate.

Performance and Specifications:
We performed testing to support the filtration performance of the MMD Tip when used with the predicate XTRAC system. The performance was within pre-defined acceptance criteria.

Discussion: There are no differences in the performance which would raise different safety or effectiveness concerns compared to the predicate.

Performance Testing:

Nonclinical / Bench:
We have performed bench tests and found that the MMD Tip when used with the XTRAC System met all requirements specifications and can be found to be equivalent in comparison to the predicate.
Testing included
- Tip Dose Accuracy and Uniformity
- Tip Transmission
- Tip Shelf Life
- Tip Shipping

In all cases the subject device met its performance criteria.

Biocompatibility:
We assessed the patient contact type and performed the applicable ISO 10993-1 tests which included:
- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

The test results supported the materials as non-cytotoxic, non-sensitizers, non-irritants, and non-toxic.

Discussion of Differences
The only difference is that the subject MMD Tip has 4 filters and allows the user to deliver difference doses in one procedure vs. multiple doses.
This difference does not raise different safety or effectiveness concerns.

**Substantial Equivalence Conclusion**
Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we have demonstrated that the MMD Tip when used with the XTRAC system, K073659, is substantially equivalent in safety and effectiveness to the predicate device.