September 14, 2018

Medtek Skincare, LLC
Susan Anthoney-Dewet
FDA Consultant
Aegis Regulatory, Inc.
2424 Dempster Drive
Coralville, Iowa 52241

Re: K180875
  Trade/Device Name: Poly Rejuv
  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: OHS
  Dated: March 16, 2018
  Received: April 3, 2018

Dear Susan Anthoney-Dewet:

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/cfpnmn/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
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,

David Krause -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

The Poly Rejuv Model 633 is intended to emit energy in the red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

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)

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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PRASStaff@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."
510(k) Summary

K180875

This 510(k) summary of information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Submission Date: March 27, 2018

1. **Submitter Information**: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
   2424 Dempster Drive
   Coralville, IA 52241
   Tel.: 865-982-5552
   Email: sue@fdalistingconsultants.com

   **On behalf of Sponsor**: MedTek Skin Care, Inc.
   3 Depot St., Hudson Falls, NY 12839

2. **General Information**

   2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction Device

   2.2 Common/Usual Name: Polychromatic LED Therapy System

   2.3 Proprietary Names: Poly Rejuv, (POLY)Model 633

   2.4 Classification: Class II

   2.5 Classification Number: 878.4810

   2.6 Product Code: OHS

   2.7 Regulation Medical Specialty: General & Plastic Surgery

   2.8 Review Panel:
   Office of Device Evaluation (ODE)
   Division of Surgical Devices (DSD)
   General Surgery Devices Branch One - Light Based/Laser (GSDB1)

3. **Predicate Device(s):**

   **3.1 Predicate Device for Model 633:**
   K162098-LED Phototherapy Device (Li-Tek Electronic Technology Corporation)

   **3.2 Reference Devices:**
   1. K150098 – LightStim Professional 2-Panel Light System (LED Intellectual)
2. **K170187- Photodynamic Therapy Device (UV Biotek, LLC (now Medtek Skin Care))**

4. **Device Description:**

The Poly Rejuv is a portable device that has a detachable treatment head, containing a total of 1,820 red LEDs in the treatment head. The treatment head is attached to a lifting stand that is attached to the main frame on a rolling stand. The user interface for applying treatment is a key lock to power ON/Off the device and a display screen attached to the main frame that runs the software (password protected-lockout code, runs treatment time/ treatment head) for the device. 12 pairs of protective eyewear are included with the device.

The device is sold as Over the Counter (OTC) to commercial establishments only and not for home use.

The Poly Rejuv is not intended to be used by laypersons. Poly Rejuv is intended to only be operated by a person who has been trained by the Sponsor according to their Customer Training Plan.

5. **Indications / Intended Use:**

The Poly Rejuv Model 633 is intended to emit energy in the red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. (Product Code: OHS)

6. **Comparison Of Technological Characteristics With The Predicate Device:**

**Table 1: Poly Rejuv Model 633 (Treatment head only contains red LEDs)**

Please note that the proposed Poly Rejuv device below is identical in technology to reference device 2: Photodynamic Therapy Device, (K170187) (Red Treatment Head).

<table>
<thead>
<tr>
<th>Device</th>
<th>Proposed Poly Rejuv Model 633</th>
<th>Predicate LED Phototherapy Device (K162098)</th>
<th>Reference LightStim Professional 2-Panel Light System (K150098)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFU</td>
<td>The Poly Rejuv Model 633 is intended to emit energy in the red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.</td>
<td>The red light is intended for the treatment of periorbital wrinkles.</td>
<td>System #1-emitting energy in the visible and IR spectrums intended for use in the treatment of full-face wrinkles</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Product Codes</strong></td>
<td>OHS</td>
<td>OHS</td>
<td>OHS</td>
<td>SE</td>
</tr>
<tr>
<td>------------------</td>
<td>-----</td>
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<td>----</td>
</tr>
<tr>
<td><strong>Wavelengths</strong></td>
<td>633nm</td>
<td>630 +/- 3nm</td>
<td>Red and Infrared</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Total Power Density</strong></td>
<td>Red: 60mW/cm²</td>
<td>Red: 80 mW/cm²</td>
<td>*65 mW/cm²</td>
<td>Similar to Predicate</td>
</tr>
<tr>
<td><strong>Treatment Regimen</strong></td>
<td>2 treatments per week for 6 weeks</td>
<td>2 treatments per week for 6 weeks</td>
<td>Unknown * daily, 5 days per week for 8 weeks per their cited predicate device.</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Treatment Time (per Tx)</strong></td>
<td>4 minutes</td>
<td>3 minutes per target area</td>
<td>Unknown * 3 minutes, per their cited predicate device.</td>
<td>Similar to Predicate</td>
</tr>
<tr>
<td><em><em>Standard Dose per treatment (mW/cm²</em> Tx time sec/1000)</em>*</td>
<td>Red: 14.4 J/cm²</td>
<td>Red: 14.4 J/cm²</td>
<td>Red and Infrared: 15.6 J/cm²</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Modes</strong></td>
<td>ON/OFF</td>
<td>ON/OFF</td>
<td>ON/OFF</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Power Supply</strong></td>
<td>100-240V, 50/60Hz±2%, 300VA</td>
<td>Lithium Battery</td>
<td>AC to DC power supply</td>
<td>Similar to Reference Device</td>
</tr>
<tr>
<td><strong>Number of LEDs</strong></td>
<td>1820 LEDs</td>
<td>Unknown</td>
<td>1130 LEDs</td>
<td>Similar to Reference Device</td>
</tr>
<tr>
<td><strong>Treatment Area</strong></td>
<td>800cm²</td>
<td>30cm²±5%</td>
<td>Unknown- 2 panels containing the LED array</td>
<td>Similar to Reference Device</td>
</tr>
<tr>
<td><strong>Type and distance from skin</strong></td>
<td>Panels containing LED array- 6cm distance from skin</td>
<td>Handheld device used 2-3 cm distance from skin</td>
<td>Panels containing LED array- unknown distance from skin</td>
<td>Similar to Reference Device</td>
</tr>
<tr>
<td><strong>Rx or OTC</strong></td>
<td>OTC-Professional Use Only with Company Training</td>
<td>OTC</td>
<td>OTC- Company Training</td>
<td>Similar to Reference Device</td>
</tr>
</tbody>
</table>
Summary of the technological characteristics of the device compared to the predicate device:

The Poly Rejuv device Model 633 has the same indications for use, wavelengths, treatment regimen, standard dose per treatment, and modes of operation with similar power output as its cited predicate device.

The main technological differences between the Poly Rejuv device and the predicate device is the number of LEDs, treatment area, type and distance used from skin (panel vs. handheld), power supply (battery vs mains), and intended operators of the device. However, the Poly Rejuv device is similar to the reference device LightStim Professional 2-Panel Light System (K150098) in these areas.

The sponsor is certain that the differences in the number of LEDs, treatment surface area, and distance used from skin (panel vs. handheld), does not affect the safety or efficacy of the device as there are a wide range of devices that have used predicate devices with different number of LEDs, different treatment areas, and panel vs handheld devices cleared under product code OHS with no clinical studies required. Performance Data i.e. bench testing and safety testing included in this submission shows that the Poly Rejuv device is at least as safe and effective as the predicate and reference devices.

7. Performance Data/Non-Clinical Testing:

The conclusions drawn from the nonclinical testing below demonstrate that the Poly Rejuv device is as safe, as effective, and performs as well as, or better than the legally marketed devices identified in section 3.

Safety Testing

The Poly Rejuv device has been tested and conforms to international consensus standards:

**ELECTRICAL SAFETY:**
- **Recognition Number 19-4:**
  - IEC60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

**EMC:**
- **Recognition Number 19-8:**

**LAMP SAFETY:**
- **Recognition Number 12-249:**

**DEVICE SPECIFIC SAFETY:**
Recognition Number 12-242:
- IEC 60601-2-57:2011 Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use

USABILITY:
Recognition Number 5-114:
- IEC 62366-1 Edition 1.0 2015-02, Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including Corrigendum 1 (2016)]. (General I (QS/RM))

Recognition Number 5-89:

The Poly Rejuv device has been tested to ensure the device meets specifications:

BENCH TESTING:
- Software Validation Testing
  The Poly Rejuv device's software was tested and validated in accordance with FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."

PERFORMANCE TESTING:
The bench tests include tests for Power Density, Timer and Functions Test, Electrical Safety Test, Use Life Test, and Storage Condition Test.

8. Substantial Equivalence Conclusion
After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicate and reference devices and no new issues arise for safety and effectiveness. Therefore substantial equivalency is hereby requested.