PS Advanced Engineering
CD Feak
President
200 South Garfield Avenue, Suite 103
Alhambra, California 91801

Re: K133546
Trade/Device Name: StarLite-OM SL-8813
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: June 30, 2014
Received: June 30, 2014

Dear Feak:

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" (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,

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

SL-8813 is an Over The Counter (OTC) handheld device intended for in the treatment of full face 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)

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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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Department of Health and Human Services
Food and Drug Administration
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."
510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92

1) General Information

Submitter: PS Advanced Engineering
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Suite 103
Alhambra, Calif. 91801

Contact Person: C D Feak
President
PS Advanced Engineering
200 South Garfield Ave
Suite 103
Alhambra, Calif. 91801

Summary Preparation Date: 24 October 2013

2) Product Code = OHS

3) Product Names:

Device Common Name: Light Based Over The Counter Wrinkle Reduction
Device Model Number: SL88-13
Trade Names: StarLite-OM, Light Effects, Thibiant
Classification Name: Laser Instrument, Surgical Powered – General and Plastic Surgery – Class II, Gen 79-GEX

Although this device is not a Laser and is intended for Over The Counter use, the manufacturer believes this is the classification name which is most applicable and is the same classification as the LightStim (K120775), Trinity Wrinkle Reducer (K120560), Baby Quasar Plus (K130225) and StarLite-LM (K092460) devices.

Indications for Use: The SL8813 is an Over The Counter (OTC) handheld device intended for use in the treatment of full face wrinkles.
4) Predicate Devices

Primary: LightStim for Wrinkles (K120775), Trinity Wrinkle Reducer (K120560), Baby Quasar Plus (K130225)
Secondary: StarLite-LM (K092460)

5) Device Description

SL-8813 is a handheld ergonomically designed ABS plastic housed device with a locking Medical Grade Stainless Steel retainer holding in place a Medical Grade USP Class polycarbonate lens from which high spectral purity LED light in 4 (four) specific wavelengths is emitted. By design the optical output has a high degree of homogenous light distribution. The output wavelengths are actuated via a simple on-off swipe button and are in the visible Red and the Infrared spectrum. SL8813 is powered by a built in (non user accessible) Lithium Ion Battery which can be charged as required via a supplied UL listed AC/DC wall mounted unit. Treatment time for light outputs is controlled by the operator as per Treatment Protocols listed in User Documentation. Audible announcement is provided to the user for timing intervals of treatments and is so noted in User Documentation.

6) Substantial equivalence in Indications for Use

The SL-8813 and the Predicate devices are hand held LED emitting devices intended for Over The Counter patient usage to specifically reduce facial wrinkles.

The target patient population for SL-8813 is identical to the population of the predicate devices.

SL-8813 and the Primary Predicate devices claim to emit identical frequencies or wavelengths of LED light energy with all claiming to meet 65mW/cm² fluence levels with specific irradiance level distributions for the wavelengths and using the same treatment methods for the same treatment areas.

All devices emit in the Red and Infrared region within the “human safe” EC 62471 AND EU DIRECTIVE 2006/25/EC classification.

7) Performance Data compliant to Predicate Devices

a) Evaluation Testing:

1) SL-8813 electro-optical performance verification of LED power densities (mW/Cm²), pattern homogenous-ness and electrical performance were conducted referencing Table 1 International Standards.

2) Safety and essential performance designed for and validated referencing Table 1 International Standards.

3) SL-8813 optical energy output fluences are set in each specific wavelength to minimally meet the claimed fluence levels in each of the specific wavelengths as the Primary Predicate devices

Based on analysis of the performance, indications for use, user demographic base, safety and effectiveness characteristics for SL-8813, PS Advanced Engineering (PSAE) believes that the SL-8813 meets all criteria claimed by the previously approved Primary Predicate Devices.
8) **Performance Data compliant to Secondary K092460**

Based on an identical physical design and fitment as well as a simpler variation of the same methods of user operation and very close to identical wording and packaging design and an identical user demographic base, PSAE believes that no significant differences in those specific characteristics exists between the SL-8813 and the previously approved StarLite-LM device (K092460).

Therefore SL-8813 raises no new questions of safety, and an addendum Usability Study was performed to evaluate Self Selection and other considerations for Human Factors – Usability comprehension to assess differences in packaging design and modified indications for use between the SL-8813 and the Secondary Predicate.

9) **Table 1 – Applied International Standards**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-3 Ed 3.0 2006-02</td>
<td>Electro Magnetic Compatibility - Testing and measurement techniques – Radiated, radio frequency, electromagnetic field immunity test</td>
</tr>
<tr>
<td>CEI/IEC 62304:2006 Ed1 2006-05</td>
<td>Medical Device Software - Software life cycle processes</td>
</tr>
<tr>
<td>IEC 61000-4-2 Ed 2.0 2008-12</td>
<td>Electromagnetic Compatibility (EMC) Testing and measurement techniques – Electrostatic discharge immunity test</td>
</tr>
<tr>
<td>EN ISO 14791:2012</td>
<td>Medical Devices – Application of risk management to Medical Devices</td>
</tr>
<tr>
<td>IEC/TR 62471-2 Ed 1.0 2009-08</td>
<td>Photobiological safety of lamps and lamp systems – Part 2 Guidance on manufacturing requirements relating to non-laser optical radiation safety</td>
</tr>
</tbody>
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10) **Clinical Testing**

There were no clinical test requirements for this submission. An addendum Usability / Self Selection study was performed.