K131712

## 3. 510(k) Summary

MAY 3 0 2014

**Submitter:**
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**Device Information**
Trade Name: A-Tone IPL System
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: ONF
Regulation Number: 21 CFR Part 878.4810
Device Class: Class II
Date of submission: 6/3/2013

**General Description**
Intense pulsed light system is a unit for general surgery and in dermatology using intense Pulsed Light system intended to cut, destroy, or remove tissue by light energy emitted by flash lamp. It is a light source with a wavelength range of approximately 530nm~1100nm.

This equipment is composed of the main body and a hand piece which is an irradiation device, and, as an accessory part, protective goggles for protection of the worker.

- Operation principle: This equipment is controlled by a micro-processor interfaced to a LCD touch screen control panel. The computer controls start and stop of the treatment and on and off of the equipment. When the key switch of the system is turned clockwise, the main power will be inputted, which will be conveyed to the hand piece through the control board.

Meanwhile, the control board connected to the touch screen is connected to the lamp of the hand piece and controls the same, and controls the whole system through the data connected to the touch screen control panel. When the switch of the hand piece is pressed, the lamp will radiate light, which will be outputted after being filtered to a certain wavelength (530nm~1100nm) by the two filters of the hand piece.

**Indication for Use**

A-tone systems are indicated for permanent hair reduction, and the treatment of benign vascular and pigmented lesions.

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

**Predicate Devices:**

The subject device is substantially equivalent to the following predicate devices:

- StarLuxTM Pulsed Light System (K041086)
- Intense Pulsed Light (IPL) Systems (K122995)

**Comparison to Predicate Devices:**

The A-Tone has a substantially equivalent intended use as the identified predicates, StarLuxTM Pulsed Light System (K041086), Intense Pulsed Light (IPL) Systems (K122995). The A-Tone IPL System is Intense pulsed light system is a unit for general surgery and in dermatology using Intense Pulsed Light system intended to cut, destroy, or remove tissue by light energy emitted by flash lamp. It is a light source with a wavelength range of approximately 530nm~1100nm. The system is same or similar to other commercially available products based on the light source, intended use, applications, the claims, the spectrum and functioning characteristics.

The A-Tone IPL system, StarLuxTM Pulsed Light System (K041086), Intense Pulsed Light (IPL) Systems (K122995) are similar in fundamental scientific technology. These predicate devices and A-tone IPL System have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document Guidance on the Content and Organization of a Premarket Notification for a Medical Laser

**Performance Data:**

All of the data consistent with the recommendations in the FDA guidance document *Guidance on the Content and Organization of a Premarket Notification for a Medical Laser.* The A-Tone IPL System has been tested and complies with the following voluntary recognized standards:

- EN 1041 [1998-02] Information supplied by the manufacturer with medical devices
- EN 980 [2003] Graphical symbols for use in the labeling of medical devices
- ISO 9001 [2008-12-15] Quality management systems
- ISO 13485 [2003-7-15] Medical devices - Quality management systems
- ISO 14971 [2007] Medical devices – Application of risk management to medical devices
- EN 60601-1 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility
- IEC 60601-1-2 [2007] Medical electrical equipment- Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1-4 [2000] Medical electrical equipment- Part 1: General requirements for Safety 4th Collateral standard: Programmable electrical medical systems
- IEC 60601-2-22 [1996] Medical electrical equipment - Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser equipment

- IEC 60825-1 [2007] Safety of laser products - Part 1: Equipment classification and requirements

**Non-Clinical Performance Data:**
Not Applicable

**Clinical Performance Data:**
Not Applicable

**Substantial Equivalence Comparison chart**

| **Product name** | **A-Tone** | **StarLuxTM Pulsed Light system** | **Intense Pulsed Light (IPL) Systems** |
|---|---|---|---|
| **Manufacturer** | AMT ENGINEERING CO.,LTD | PALOMAR MEDICAL PRODUCTS, INC | Beijing KES Biology Technology Co., Ltd. |
| **510(k) number** | current submission | K041086 | K122995 |
| **Light source** | Intense Pulsed Light | Intense Pulsed Light | Intense Pulsed Light |
| **emitted by** | flash lamp | flash lamp | flash lamp |
| **accessories** | Hand piece, foot switch, goggles | Hand piece, foot switch, goggles | Hand piece, foot switch, goggles |
| **Operation** | touch screen | touch screen | touch screen |
| **Intended use** | A-tone system is intended use for permanent hair reduction, and the treatment of benign vascular and pigmented lesions. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. | The StarLuxTM System is intended for treatment of inflammatory acne and for the treatment of cutaneous lesions, including warts, scars and striae. | The Intense Pulsed Light (IPL) Systems (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in permanent hair removal, skin rejuvenation, reduction of pigmented lesions, acne therapy, freckle, vascular lesions and facial blemish removal. |
| **Energy spectrum** | 530nm-1100nm | 400-1200nm | 430nm~1200nm |
| **Spot size** | 12 x 38mm | 16x46mm, 12x28mm, 10 x 15 mm | 12mm X 50mm |
| **Fluence** | Up to 25J/cm$^2$ | Up to 50 J/cm2 | Up to 60J/cm$^2$ |

| | | | |
|---|---|---|---|
| **Pulse type** | Single, multiple | Single | single, multiple |
| **Pulse duration** | 1-20ms | 1-500 ms | 1~20ms |
| **Pulse delay** | 5-60ms | N/A | 5~50ms |
| **Repetition rate** | 1Hz | up to 2Hz | 0.2Hz; 2Hz |
| **delivery system** | Direct coupling through coated filter light guide | Direct coupling through coated filter light guide | Direct coupling through coated filter light guide |
| **Electrical requirements** | AC 230 V, 50 Hz, 9A | 100-240 V, 50/60 Hz | 220V±20V 50Hz or 110V±20V, 60Hz |
| **Cooling method** | Continuous contact cooling | Continuous contact cooling | Continuous contact cooling |
| **device classification** | II:21 CFR 878.4810 | II:21 CFR 878.4810 | II:21 CFR 878.4810 |
| **Product Code** | ONF | GEX | ONF |
| **Delivery system** | BK7 | Bk7, fused silica, sapphire | Sapphire |

**Safety and Effectiveness**

The A-Tone IPL system and predicate devices are same or similar in light source, range of spectrum, application, and are non- sterilized products. Differences in the specifications between the A-tone IPL system and the predicates do not result in different performance or raise new questions of safety or effectiveness.

The safety features in the A-Tone IPL System are substantially equivalent to the safety features found in the predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the A-Tone IPL System underwent performance testing, including software validation testing, electrical and mechanical safety testing according to EN 60601-1, electromagnetic compatibility testing according to IEC 6060 1-1-2. These performance tests demonstrated that the minor differences in the device software and specifications meet the system requirements and do not raise new safety or effectiveness concerns. Thus, the A-Tone IPL system should not raise new issues of safety and effectiveness and is judged to be substantially equivalent to the mentioned predicate devices to be legally marketed in the USA.

**Conclusions:**

Based on the performance testing and comparison to predicate devices, the A-Tone IPL system is substantially equivalent to the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 30, 2014

YBK Investment Incorporated
% Ms. Joyce Bang
Provision Consulting Group
1915 White Star Drive
Diamond Bar, California 91765

Re: K131712
Trade/Device Name: A-Tone IPL system
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: ONF
Dated: May 8, 2014
Received: May 13, 2014

Dear Ms. Bang:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K131712

Device Name
A-Tone IPL system

Indications for Use *(Describe)*

A-tone systems are indicated for permanent hair reduction, and the treatment of benign vascular and pigmented lesions. Permanent hair reduction is defined as the long-term, 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.05.30 15:03:02 -04'00'

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