K101901

Section 1 **510(k) Summary**

MAR - 8 2011

Prepared Date: Jul. 02, 2010
As required by 807.97
The assigned 510(k) Number is _____

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Submission Correspondent	Ms. Diana Hong / Mr. Tarzan Wang Shanghai Mid-Link Business Consulting Co., Ltd Sute 5D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: 240-238-7587 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	IPL Therapy Systems
Model	ST-AI
Product Code:	ONF
Regulation Number:	21 CFR 878.4810
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	GSD INTENSE PULSED LIGHT SYSTEM (K091664) Angelite Family of Intense Pulsed Light System (K083915)
Device Description	The IPL Therapy Systems (ST-AI) is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 640nm-1200nm. Intense Pulsed Light (IPL) systems work on the principles of selective photothermolysis..That is, causing thermal damage to target chromophores by using light of appropriate wavelength in

	pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin. IPL Therapy system is different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores. Based on this, the IPL Therapy Systems (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in the hair removal.
Test Conclusion	The IPL Therapy Systems is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including: IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests (Edition 2: 2001 with Amendment 1: 2004; Edition 2.1 (Edition 2: 2001 consolidated with Amendment 1:2004)
SE Determination	The proposed device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.
Intended Use/Indication for Use	The IPL Therapy Systems (inclusive of the handpieces used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in the hair removal at a wavelength ranging from 640nm-1200nm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Beijing Starlight Science and
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Ms. Diana Hong
Suite 5D, No. 19, Lane 999
Zhongshan No. 2 Road (S)
Shanghai, 200030, China

MAR - 8 2011

Re: K101901
Trade/Device Name: IPL Therapy Systems
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: February 25, 2011
Received: February 25, 2011

Dear Ms. Hong:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): Pending

Device Name: IPL Therapy Systems (ST-A)

Indications for Use:

The IPL Therapy Systems (inclusive of the handpieces used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in the hair removal.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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