

# Section 1 510(k) Summary

MAR - 8 2011

Prepared Date: Jul. 02, 2010

As required by 807.97

The assigned 510(k) Number is \_\_\_\_\_

**Sponsor**

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**Submission  
Correspondent**

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**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.



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

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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.

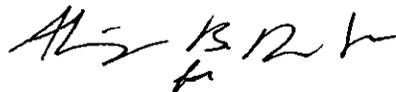
Page 2 – Ms. Diana Hong

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)

Michael R. Dyer for man  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K101901

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