K 123435

FEB 1 1 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	Sep 20,2012
Submitter:	Beijing Sincoheren Science & Technology Development Co.,Ltd B-1105 Sinotrans Plaza 43# Xizhimen BeiDajie, Haidian District, Beijing, 100044, China
Primary Contact Person:	Mr. Xin Wang Quality Manager Beijing Sincoheren Science & Technology Development Co.,Ltd Tel: +86-(0)10-82294249-8002 Fax: +86-(0)10-82294249-8007
Secondary Contact Person:	Mike Gu Regulatory Manager Guangzhou Osmunda Medical Device Consulting Co., Ltd Tel: +86-20-62321333 Fax: +86-20-86330253
Device: Trade Name:	IPL Therapy System
Common/Usual Name:	Intense Pulsed Light Therapy System
Classification Names:	Powered Light Based Non-Laser Surgical Instrument with Thermal Effect
Product Code:	ONF
Regulation Number:	21 CFR 878.4810
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device(s):	K093627 IPULSELIGHT IPL SYSTEM
Model	SMQ-NYC; SMQ-NK
Device Description:	The IPL Therapy Systems is an Intense Pulsed Light Therapy System which delivers intense pulsed light at a wavelength ranging from 690nm -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 appropriated 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.

The Sincoheren IPL Therapy system controlled by computer is composed:

- Main unit
- LCD monitor
- Treatment handle

The embedded microprocessor monitors can control the system continually.

The operating Interface includes a full-LCD screen (8.0 inch), the key switch and emergency shut-off knob.

LCD screen both shows the system work program, treatment parameters and number of light emitting. The treatment handle operated by hand comprises the intense emitter and transmission system.

Differences between two models:

The differences between SMQ-NYC and SMQ-NK are:

- The installation method was changed from stationary to mobile;
- The product shape:

	Differences	SMQ-NK	SMQ-NYC
1	Overall size (W*D*H)	840mm*600mm*500mm	490mm*525mm*952mm
2	Overall size of cooling condenser	170mm*160mm*37mm	305mm*160mm*61mm

Please see the Appendix A for IEC 60601-1 test report.

the IPL Therapy Systems is designed, tested, and will be manufactured in accordance with both mandatory and voluntary standards:

1. IEC 60601-1Medical equipment medical electrical

equipment - Part 1: General requirements for basic safety and essential performance 1988+A1 : 1991 + A2:1995

2. IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Intended Use: The intense pulsed light therapy system is indicated for use in surgical, aesthetic and cosmetic application in the hair removal at a wavelength ranging from 690nm – 1200nm.

Technology: Proposed device and predicate device use a light based Non-Laser device that provides thermal effect including broad spectrum source devices such as Intense Pulse Light. Both devices emit Intense Pulsed Light (IPL) using Xenon Lamp.

The proposed device emits IPL at a wavelength ranging from 690nm-1200nm. The unit composes three parts: the main unit, control panel and treatment handle.

The Intense Pulsed Light Therapy System employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Intense Pulsed Light Therapy System and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Raw materials verification
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)

- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Intense Pulsed Light Therapy System, did not require clinical studies to support substantial equivalence.

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.

Conclusion: Beijing Sincoheren Science & Technology Development Co., Ltd considers the Intense Pulsed Light Therapy System to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

Beijing Sincoheren S&T Development Company, Limited
% Guangzhou Osmunda Medical Device Consulting Company
Mr. Mike Gu
Regulatory Manager
7th Floor 982 Congyun Road, Baiyun District
Guangzhou, Guangdong
China 510420

February 11, 2013

Re: K123435
Trade/Device Name: Intense Pulsed Light Therapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONF
Dated: December 20, 2012
Received: December 26, 2012

Dear Mr. Gu:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, For

Peter D. Rümm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123435

Device Name: Intense Pulsed Light Therapy System

Indications for Use:

The intense pulsed light therapy system is indicated for use in surgical, aesthetic and cosmetic application in the hair removal at a wavelength ranging from 690-1200nm.

CONDITIONS		SKIN TYPES					
		I	II	III	IV	V	VI
HAIR REMOVAL	Wave length (nm)	690-1200	690-1200	690-1200	690-1200	690-1200	N/A
	Density	35-45J/cm^2	30-40 J/cm^2	25-30 J/cm^2	20-35 J/cm^2	20-25 J/cm^2	-
	Program	Program3	Program2	Program2	Program1	Program1	-

Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.02.08 15:30:58 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123435