Section 3 510(k) Summary

NOV 16 2009

As required by 807.97

The assigned 510(k) Number is K091664

Page 1 of 2

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Submission Correspondent	Ms. Diana Hong / Mr. Tarzan Wang Shanghai Mid-Link Business Consulting Co., Ltd Sute 8D, 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	GSD Intense Pulsed Light System
Model	GP666C4 & GP666C
Product Code:	GEX
Regulation Number:	21 CFR 878.4810
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	Angelite Family of Intense Pulsed Light System (K083915) SkinStation System(K030897) Radiancy Mistral Device(K072331)
Device Description	The GSD Intense Pulsed Light System (GP666C4 and GP666C) is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 400nm-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.
Test Conclusion	The GSD Intense Pulsed Light system 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 GSD Intense Pulsed Light System (inclusive of the handpieces used to deliver pulsed-light energy) is indicated for use in surgical, asthetic and cosmetic applications in the treatment of acne , treatment of benign pigmented lesions, hair removal, treatment of vascular lesions as following: 1. Intense Pulsed Light energy wavelengths from 500-1200nm are indicated for the treatment of pigmented lesions, hair removal, and treatment of vascular lesions. 2. Intense Pulsed Light energy wavelengths from 400nm-1200nm are indicated for the treatment of acne. 3. Intense Pulsed Light energy wavelengths from 750nm-1200nm are indicated for the treatment of benign pigmented lesions, hair removal, and treatment of vascular lesions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 16 2009

Shenzhen GSD Tech Co., Ltd.
% Shanghai Mid-Link
Business Consulting Co., Ltd.
Ms. Diana Hong, General Manager
Suite 8D, No. 19, Lane 999
Zhongshan No. 2 Road(S)
Shanghai, 200030, China

Re: K091664
Trade/Device Name: GSD Intense Pulsed Light 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: November 5 2009
Received: November 9, 2009

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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 K091664

Device Name: GSD Intense Pulsed Light System

Indications for Use:

The GSD Intense Pulsed Light System (inclusive of the handpieces used to deliver pulsed-light energy) is indicated for use in surgical, asthetic and cosmetic applications in the treatment of acne , treatment of benign pigmented lesions, hair removal, treatment of vascular lesions as following:

1. Intense Pulsed Light energy wavelengths from 500-1200nm are indicated for the treatment of pigmented lesions, hair removal, and treatment of vascular lesions.
2. Intense Pulsed Light energy wavelengths from 400nm-1200nm are indicated for the treatment of acne.
3. Intense Pulsed Light energy wavelengths from 750nm-1200nm are indicated for the treatment of pigmented lesions, hair removal, and treatment of vascular lesions

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)

Nick Pyo for mxm

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

510(k) Number K091664