DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2016

Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
Mr. Jonathan Hu
Medwheat (Shanghai) Medical Technology Co., Ltd.
Yangpu District
Liaoyuan East Road Shuangyang First Suite No. 33 Room 303
Shanghai, Shanghai China 200093

Re: K161356
Trade/Device Name: Matrix LS-40 CO2 Laser 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: GEX
Dated: July 25, 2016
Received: August 3, 2016

Dear Mr. Hu:

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 Part 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 Parts 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,

Christopher J. Ronk -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)*
K161356

Device Name
Powered Laser Surgical Instrument

Indications for Use *(Describe)*
It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

The CO2 System is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery, general surgery.

Dermatology, Plastic Surgery and General Surgery procedures:
• Laser skin resurfacing.
• Treatment of furrows and wrinkles.
• Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.
• Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
• Blepharoplasty.
• Site preparation for hair transplants.
• The fractional scanner is for skin resurfacing.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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002_510(k) Summary

Date Prepared:September 9, 2016

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
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2. Correspondent's Information

CompanyName:	Med-wheat Shanghai
Correspondent Name:	Jonathan Hu
Telephone No.:	0086-021-65181421
Email Address:	Jonathan.hu@medwheat.com

3. Trade Name, Common Name, Classification

Trade Name:	Matrix LS-40 CO2 Laser System
Common Name:	Medical Laser System
Mode Name:	Matrix LS-40
Regulation Classification	Powered Laser Surgical Instrument
Product Code:	GEX
Classification Panel:	General and Plastic Surgery
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicatedevice within this submission is as follows:

TheCortex Laser System of Cynosure, Inc. dbaEllmanhas been cleared by FDA through 510(k) No.K150587 (Decision Date – July 21, 2015).

5. Description of the Device

The MATRIX LS-40 CO2 Surgical laser System is a system incorporating a permanently articulated arm that delivers CO2 laser power in a wavelength of 10,600nm in its normal operations. The device is activated by means of a footswitch.

The Laser System is designed for use in an office or a clinic, which shall be a clean, dry and well-ventilated room with a door.

6. Indication for Use

It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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•Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basal cell carcinoma, warts and uneven pigmentation.

• Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.

• Blepharoplasty.

• Site preparation for hair transplants.

• The fractional scanner is for skin resurfacing.

7. Technological Characteristics

The subject device in this 510(k) uses the same technology that is utilized in the predicate device. A comparison of technological characteristics is provided in the following table:

Items		Matrix LS-40 CO2Laser System	Cortex Laser System in K150587
Technology Characteristics			
Laser Type		Sealed CO2 Laser Tube	Sealed CO2 Laser Tube
Wavelength		10.6 micron (10,600nm)	10.6 micron (10,600nm)
Laser Operation Mode		Continuous Wave (CW), Blend (PW), Super Pulse (SP)	Continuous Wave, Blend (PW), Super Pulse
Power to Tissue	CW	0.5-40W	0.5-40W
	PW	0.5-30W	0.5-30W
	SP	0.5-15W	0.5-15W
Frequency Range	CW	N/A	N/A
	PW	30Hz	30Hz
	SP	20-240Hz	20-240Hz
Peak Power		200W	200W
Repetition Rate		1-8 Hz/240 Hz Super Pulse	1-8 Hz/240 Hz Super Pulse
SuperPulse Duration		10-1000ms	10-1000ms
Aiming Beam		3mW (650nm diode) adjustable	3mW (650nm diode) adjustable
Spot Size		100μm for surgical handpiece 150μm for fractional handpiece	100μm for surgical handpiece 150μm for fractional handpiece
Articulated Arm		7-joint articulated arm	7-joint articulated arm
Cooling Type		Closed Loop Liquid	Closed Loop Liquid
User Interface		LCD Touch Screen	LCD Touch Screen
Dimension		34cm*46cm*96cm	150cm*46cm* 31cm
Weight		46.5Kg	60kg
Power Input		110 - 120 VAC, 10 A, 50-60 Hz	110 - 120 VAC, 10 A, 50-60 Hz

8. Discussion of Non-clinical Testing

The Matrix LS-40 CO2 Laser System has been conducted related non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of electrical safety, EMC and the requirements of radiation safety, which contains the standards including IEC 60601-1:2005/COR1:2006/COR2:2007, IEC 60601-1-2:2007, IEC 60601-2-22:1995 and IEC 60825-1:2007.

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, it is concluded, basing on performance testing, indication for use, and technology, the subject device is substantially equivalent to the predicate device K150587.

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