K100590
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Attachment 5
510(K) Summary
Edge CO2 Laser System

NOV 1 0 2010

This 510(K) Summary of safety and effectiveness for the Edge CO2 laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	JM System Co., LTD
Address:	410, Daerung Techno Town 8th 481-1, Gasan-dong Geumcheon-gu Seoul, Korea 153-775
Contact Person:	Mr. Su-Gun Lee
Telephone: Fax: Email:	82(02)2163-0158 – phone +82(02)2163-8932 – fax didvkd@gmail.com
Preparation Date:	February 15, 2010
Device Trade Name:	Edge CO2 Laser System
Common Name:	CO2 Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-ONG, 21 CFR 878-4810
Legally Marketed Predicate Device:	Cynosure Affirm CO2 Laser K081424
Description of the Edge CO2 laser	The Edge CO_2 laser has a wavelength of 10,600nm. CO_2 fractional laser uses scanning optics to deliver a pattern of thermal energy to the epidermis and upper dermis. Device accessories include tip attachments. This system consists of main body, color touch screen, Arm, hand-piece and Foot switch.
Intended use of the Edge CO2 laser	The Edge CO 2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues. The Edge CO 2 laser when used in fractionated mode is indicated for ablative skin resurfacing.
Performance Data:	A study was conducted to show the depth of penetration for each microdot using histology on pigs.
Results of Clinical Study:	None
Conclusion:	The Edge CO2 Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.

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

JM System Co., Ltd.
% Mr. Su-Gun Lee
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Seoul, Korea 153-775

NOV 10 2010

Re: K100590
Trade/Device Name: Edge 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: ONG
Dated: October 18, 2010
Received: November 09, 2010

Dear Mr. Lee:

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

Indications for Use

NOV 10 2010

510(k) Number (if known): K 100590

Device Name : Edge CO2 Laser System

The Edge CO 2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues.

The Edge CO 2 laser when used in fractionated mode is indicated for ablative skin resurfacing.

Prescription Use xx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100590