APR - 2 2004

K033888

Section E - 510(k) Summary

Submitted by:

MedSphere International, Inc.

48511 Warm Springs Blvd., Suite 212, Fremont, CA 94539

Tel: 510-656-8232 Fax: 510-656-8816

Contact Person:

Eric Kao, Vice President of Quality and Regulatory Affairs

Date Summary Prepared:

December 12, 2003

Name of the Device:

Trade / Proprietary Name: MSI S-500 RF Generator

Common / usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical cutting and coagulation device (21CFR878.4400)

Predicate Devices:

Somnus Model 225 Electro Surgical Generator (K963772)

Description:

MSI S-500 RF Generator

Statement of Intended Use:

MSI S-500 RF Generator is intended for coagulation of soft tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:

MSI S-500 RF Generator has been compared to previously 510(k) cleared device with respect to intended use and technological characteristics. Performance testing was done to validate its intended use. The comparison and performance testing results in this 510(k) notification shows MSI S-500 RF Generator is substantially equivalent to predicate device and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Mr. Eric Kao
Vice President of Quality and Regulatory Affairs
Medsphere International, Inc.
48511 Warm Springs Boulevard, Suite 212
Fremont, California 94539

Re: K033888
Trade/Device Name: MSI S-500 RF Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 2, 2004
Received: March 4, 2004

Dear Mr. Kao:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section D - Statement of Indications for Use

K033888

Indications for Use

Applicant:	MedSphere International, Inc. 48511 Warm Springs Blvd., Suite 212, Fremont, CA 94539
510(k) Number (if known):	
Device Name:	MSI S-500 RF Generator
Indications For Use:	Indicated for coagulation of soft tissue These devices are intended for use by qualified medical personnel trained in the use of electrosurgery.

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

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033888

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional format 1-2-06)