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FEB 2 7 2006

K060046

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Corporate Address:**	MedicSense, Ltd. 14 Imber Kiriat Arie, Petach Tikva, Israel 49511 www.medicsense.com
1. (b)	***Manufacturer Address:***	EnzySurge, Ltd. 63 Ha ' Odem St. POB 1 Shoham, Israel 73142
	Mfg. Phone:	972-3-979-6344
	Contact Person:	Dr. Allon Leibovitz, CEO
	Date:	January 4, 2006
2.	***Device & Classification Name:***	Dressing, wound and burn occlusive (Class 1), Product Code NAD, 21 CFR 878.4020- Trade-name of device: DermaStream™
3.	***Predicate Device:***	KCI Wound Cell Transparent Wound Dressing (K020781) 3M Tegaderm Transparent Dressing (K973036 & K901845) KCI V.A.C. Instillamat (K021501)
4.	***Description:***	The DermaStream™ is an occlusive wound dressing which permits the introduction of topical wound treatments. It is provided as a sterile, single-use, disposable device.
5.	***Intended Use:***	The DermaStream™ is an occlusive wound dressing which permits the introduction of other topical wound treatments such as irrigating solutions, antimicrobial and enzymatic debriding solutions, suspensions, and other solutions. It is intended to provide a moist healing environment and to allow debridement to facilitate the normal wound healing process.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the DermaStream™ is substantially equivalent to its predicate devices. This is because it is a combination of the fundamental features and characteristics of its predicate devices. The primary difference is the ability to provide a solution and drainage to the protected wound via gravity versus a vacuum provided by electrical power.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

EnzySurge, Ltd.
c/o Mr. George J. Hattub, RAC, CQE
Senior Staff Consultant
MedicSense, Ltd.
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K060046
Trade/Device Name: DermaSteam™
Regulation Number: 21 CFR 878.4020
Regulation Name: Occlusive wound dressing
Regulatory Class: I
Product Code: NAD
Dated: January 4, 2006
Received: January 6, 2006

Dear Mr. Hattub:

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" (21 CFR 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060046

Device Name: DermaStream™

Indications For Use: The DermaStream™ is an occlusive wound dressing which permits the introduction of topical wound treatments such as irrigating solutions, antimicrobial and enzymatic debriding solutions, suspensions, and other solutions. It is intended to provide a moist healing environment and allow debridement to facilitate the normal wound healing process.

Prescription Use X 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 General, Restorative, and Neurological Devices

510(k) Number K060046