K063517

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HEALADEX®-P 510(k) SUMMARY

(510(K) Summary, Required Under 21 CFR 807.87(h))

COMPANY (APPLICANT) NAME AND ADDRESS

HEALAGENICS
800 West Cummings Park
Suite 2900
Woburn, MA. 01801

CONTACT PERSON

Contact Name: Paul Strati, CEO
Ph: 781-376-4114 / Fax 781-376-4115
Cell: 781-775-1050

MEDICAL DEVICE INFORMATION

Proprietary Name	HEALADEX®-P Occlusive Dressing
Common Names	Wound Dressing
Classification Name	Dressing, Wound and Burn, Hydrogel, with drug or biologic

DEVICE CLASSIFICATION INFORMATION

Regulatory Class: Unclassified

Product code: FRO, KGN

STATEMENT OF SUBSTANTIAL EQUIVALENCE

HEALADEX®-P Dressing is substantially equivalent to the following approved products in indications, and to Gelita-spon Absorbable Gelatin sponge for porcine biomaterial source.

- ✓ Nu-Gel Wound Dressing (K983362) manufactured by Johnson & Johnson Medical Inc.,

- ✓ Collatek Hydrogel (K022995) manufactured by Biocore Medical Technologies, Inc.
- ✓ Woun'Dres Collagen Hydrogel Wound Dressing (K991202) manufactured by Coloplast Corporation

Indications for Use

HEALADEX®-P Wound Dressing provides a moist environment that is supportive of wound healing. HEALADEX-P is indicated for dry, light and moderately exudating partial and full thickness wounds such as:

- ✓ First and second degree burns
- ✓ Severe sunburns
- ✓ Superficial injuries, superficial lacerations, cuts, abrasions, incisions/surgical wounds, and skin tears

HEALADEX-P dressing should be used under health care professional direction for the following indications:

- ✓ Pressure ulcers, Stage I-IV
- ✓ Lower extremity ulcers
- ✓ Venous ulcers
- ✓ Arterial ulcers
- ✓ Ulcers of mixed etiology
- ✓ Diabetic ulcers
- ✓ Donor sites and skin grafts
- ✓ Burns caused by radiation oncology procedures

Device Description and Principles of Operation

HEALADEX-P is a sterile wound-dressing comprised of carboxymethylcellulose and lyophilized formulated porcine plasma, which is island mounted on moisture vapor permeable adhesive film dressing sheet coated with acrylic adhesive and a polyurethane protective film. This dressing aids the healing process by maintaining a moist environment at the wound site.

HEALADEX-P dressing is individually packaged in a foil moisture barrier chevron peel pouch appropriately labeled with lot number and expiration date. Five units are packaged into a cardboard box with Instructions for Use (IFU).

BIOCOMPATIBILITY

Safety testing was conducted in accordance with ISO 10993 Part1 in support of the claim of biocompatibility for this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HEALAGENICS, Inc.
% Mr. Paul Strati
CEO
800 West Cummings Park
Suite 2900
Woburn, Massachusetts 01801

FEB 1[illegible] 2007

Re: K063517
Trade/Device Name: HEALADEX®-P Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO, KGN
Dated: November 1, 2006
Received: November 21, 2006

Dear Mr. Strati:

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" (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K063517

Indications for Use

510(k) Number (if known): K063517

Device Name: HEALADEX®-P Wound Dressing

Indications For Use:

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Prescription Use X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

Sign-Off

Restorative

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K063517