SECTION 2 – 510(k) SUMMARY

FEB 1 4 2002

PROMOGRAN Matrix Wound Dressing

Submitter's Name and Address:	Johnson & Johnson Medical Ltd. Gargrave SKIPTON North Yorkshire BD23 3RX United Kingdom
Contact Person	Sergio Gadaleta, PhD Senior Project Manager Johnson & Johnson Wound Management Worldwide a Division of Ethicon, Inc. Telephone: 908-218-2893 Facsimile: 908-218-2595 e-mail: sgadalet@ethus.jnj.com
Name of Medical Device	Classification Name: Dressing, Wound Common/Usual Name: Dressing Proprietary Name: PROMOGRAN Matrix Wound Dressing
Substantial Equivalence	PROMOGRAN Matrix Wound Dressing is substantially equivalent to: FIBRACOL Plus Collagen Dressing with Alginate (K982597) manufactured by Johnson & Johnson Medical Ltd., Gargrave, SKIPTON, BD23 3RX, United Kingdom
Device Classification	Currently, wound dressings containing animal derived materials are unclassified by United States Food and Drug Administration's Center for Devices and Radiological Health
Device Description	PROMOGRAN Matrix Wound Dressing is a sterile primary dressing comprised of a freeze-dried composite of 55% collagen and 45% oxidised regenerated cellulose. (Ratios are presented as weight-to-weight).

Indications for Use	The PROMOGRAN Matrix Wound Dressing is indicated for the management of exuding wounds including: • Diabetic ulcers • Venous ulcers • Ulcers caused by mixed vascular etiologies • Full thickness and partial thickness wounds • Donor sites and other bleeding surface wounds • Abrasions • Traumatic wounds healing by secondary intention • Dehisced surgical wounds
Safety	Biocompatibility studies have demonstrated PROMOGRAN Matrix Wound Dressing to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2002

Johnson & Johnson Medical Ltd.
c/o Sergio Gadaleta, Ph.D.
Senior Project Manager
Johnson & Johnson Wound Management Worldwide
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876

Re: K014129
Trade/Device Name: PROMOGRAN
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 13, 2001
Received: December 17, 2001

Dear Dr. Gadaleta:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

INDICATIONS FOR USE

510(k) Number (if known): K014129

Device Name: PROMOGRAN Matrix Wound Dressing

Indications for Use:

PROMOGRAN Matrix Wound Dressing is intended for the management of exuding wounds including:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full thickness and partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

Miriam C. Provost

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

510(k) Number K014129