DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

Medline Industries, Inc.
% Mr. Matt Clausen
One Medline Place
Mundelein, Illinois 60060

Re: K071552
Trade/Device Name: Puracol Plus Ag Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 17, 2008
Received: April 18, 2008

Dear Mr. Clausen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use

510(k) Number (if known): K071552

Device Name: Puracol® Plus Ag MicroScaffold™ Wound Dressing

Indications for Use:

Puracol® Plus Ag MicroScaffold™ Wound Dressing is indicated for the management of:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Dehisced wounds
- Surgical wounds
- Dehisced surgical wounds

These dressings may be cut to size and may be layered for the management of deep wounds.

PRECAUTIONS:
Puracol® Plus Ag wound dressings are suitable for use under compression therapy with healthcare professional supervision. Wounds with diagnosed infection may be managed with Puracol® Plus Ag dressings only when the causes of infection are being treated in parallel by medical professionals. The dressing is not intended for the treatment of infected wounds, and cannot be considered to be a substitute for proper management of infections.

CONTRAINDICATIONS:
Puracol® Plus Ag cannot be used on patients who are allergic to collagen or silver. Product use should be discontinued should signs of sensitization occur. The product is not indicated for the treatment of third degree burns.

Neil R Ogden for mxm

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

Prescription Use ___xx___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number K071552

Concurrence of CDRH, Office of Device Evaluation (ODE)