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510(k) Summary

Summary Information:

OCT 30 2008

- Submitters Name and Address: Applied Nutritionals
  1890 Bucknell Drive
  Bethlehem, PA 18015

- Contact Person: Anita Petito
  Director of Marketing
  Phone: 610-865-9876
  E-Mail: apetito@hymed.com

- Establishment Number: 2530949

- User Fee ID Number: MD6036808-956733

- Date of Summary Preparation: June 9, 2008

- Name of Device:

  - Proprietary: Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, polysulfated glycosaminoglycan) Wound Gel
  - Common: Moist wound gel
  - Classification Name: Hydrophilic Wound Dressing

- Medical Device Classification: Unclassified

- Identification of predicate devices to which substantial equivalence is being claimed:

  - HyCure® Hydrolyzed Collagen K955506
  - HeliDerm™ Collagen Wound Dressing K990086
  - Integra ® Bilayer Matrix Wound Dressing K021792
  - Chondroprotec® (10% Polysulfated GlycosaminoGlycan) K961930
  - Integra® Flowable Wound Matrix K072113

Description of the Device: Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan) Wound Gel is a line extension of the previously approved HyCure® Hydrolyzed Collagen (K955506). Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan) contains Chondroitin Sulfate as Chondroprotec® previously approved for market via 510(k) (K961930). Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel contains a high concentration of water bound to the hydrolyzed collagen which maintains a moist wound environment as it manages wound healing. Hydrolyzed Collagen with 10% Chondroitin Sulfate (PSGAG, Polysulfated glycosaminoglycan)

Wound gel is provided in a patient ready, one (1) ounce, collapsible tube.

- Intended use of the Device: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel is an absorbent wound dressing that provides a moist wound environment. As an Rx, Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel is useful in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites. As an Over the Counter preparation, Hydrolyzed Collagen with 10% Wound Gel is useful in the management of minor abrasions, lacerations, minor cuts and minor scalds and burns. Contraindicated for individuals with a known sensitivity to bovine or collagen.

- Technology Characteristics: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel is an aqueous hydrogel identical in formulation to HyCure® Hydrolyzed Collagen Wound Gel (K955506) combined with Chondroprotec® (K961930). Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel contains 10.0% Polysulfated glycosaminoglycan for the purpose of improving wound fluid retention within the gel and facilitating fibroblast mobility within the wound as in predicate products currently in commercial distribution. Chondroprotec® (10% Chondroitin Sulfate) is currently approved for market (K961930) for use in the identical indications as referenced herein. This particular formulation does not affect the intended use or alter the fundamental scientific technology of the device.

- Non-Clinical Performance Data: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

    - Agar Overlay (direct contact) Cytotoxicity testing (Exhibit I) indicated a grade 0 cytotoxic grade.
    - ISO Intracutaneous reactivity (Irritation) testing indicates a non-irritant
    - Repeat Patch Dermal Sensitization Test (Buehler Method) indicates the product is a non-sensitizer.

Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel has not been studied in a clinical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2008

Applied Nutritionals
% Ms. Anita Petito
President
1890 Bucknell Drive
Bethlehem, Pennsylvania 18015

Re: K081724
Trade/Device Name: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 10, 2008
Received: October 17, 2008

Dear Ms. Petito:

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

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Rx Indications for Use

510(k) Number: K081724

Device Name: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel

Indications for Use:

Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound gel is indicated for topical use in the management of chronic and acute wounds and dermal ulcers including the local management of:

- Pressure Ulcers (Stage I-IV)
- Venous Stasis Ulcers
- Diabetic Ulcers
- First and Second Degree Burns
- Surgical wounds
- Traumatic wounds
- Superficial wounds
- Ulcers resulting from arterial insufficiency
- Grafted wounds and donor sites

Contraindications:

- Contraindicated for individuals with a known sensitivity to bovine or collagen

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 OF NEEDED)

Neil R Ogden for mac

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

510(k) Number K081724

Over the Counter (OTC) Indications for Use

510(k) Number: K081724

Device Name: Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel

Indications for Use:

- For over the counter use, Hydrolyzed Collagen with 10% Chondroitin Sulfate Wound Gel may be used for:
    - minor abrasions
    - lacerations
    - minor cuts
    - minor scalds and burns

Contraindications:

- Contraindicated for individuals with a known sensitivity to bovine or collagen

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

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

Neil R. P. Ogden for KM

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

510(k) Number K081724