K092878

PRUGEN
IP HOLDINGS, INC.

**510(k) Summary**

**Date Prepared: September 9, 2009**

JAN 15 2010

1. **Owner's Name:**

**PruGen, IP Holdings Inc.**
8711 East Pinnacle Peak Road
Suite C-201
PMB 225
Scottsdale, AZ 85255

**Contact Person:**
**Robert L. Knechtel, M.D., J.D.**
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2. **Proprietary Name:** PruTect™ Topical Emulsion
**Common Name:** Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic
**Classification Name:** Dressing, Wound & Burn, Hydrogel w/ Drug or Biologic (Product Code MGQ)

3. **Substantially Equivalent Device:**

PruGen IP Holdings, Inc. believes that PruTect™ Topical Emulsion is substantially equivalent to the following currently marketed device: Biafine® Topical Emulsion cleared under K964240.

4. **Device Description:**

PruTect™ Topical Emulsion is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for prescription (requiring a physician diagnosis disease state) use in both 45 gm and 90 gm tube formats.

5. **Intended Use of the Device:**

PruTect™ is a water-based emulsion formulated for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound, PruTect™ provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.

6. **Summary of Technical Characteristics of Device compared to Predicate Devices**

The referenced predicate device is a non-sterile emulsion that is applied to relieve the symptoms of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis.

7. **Conclusions:**

Functional and performance testing has been conducted to assess the safety and efficacy of PruTect™ Topical Emulsion and the results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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PruGen IP Holdings, Inc.
% Robert L. Knechtel, M.D., J.D.
EVP and General Counsel
8711 E. Pinnacle Peak Road, Suite C-201, PMB 225
Scottsdale, Arizona 85255

Re: K092878
Trade/Device Name: PruTect™ Topical Emulsion
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 7, 2009
Received: January 8, 2009

Dear Dr. Knechtel:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

## INDICATIONS FOR USE

**Device Trade Name:** PruTect™ Topical Emulsion

**510(k) number: K092878**

FOR TOPICAL DERMATOLOGICAL USE ONLY

**PruTectTM is indicated for use in:**

- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers
- Superficial Wounds
- 1st and 2nd Degree Burns, including Sunburns
- Dermal Donor and Graft Site Management
- Radiation Dermatitis
- Minor Abrasions

Prescription Use ___X___ Over the counter use _____

(Part 21 CFR 801 Subpart D)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092878