K093156
page 1 of 2

510(k) Summary

Date Prepared: June 22, 2010

JUN 24 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

(T): 480-563-2406
(F): 815-261-5953
(E): rknechtel@prugen.com

2. **Proprietary Name:** PruClair™ non-steroidal cream
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 Devices:** PruGen, Inc. believes that PruClair™ non-steroidal cream is substantially equivalent to the following currently marketed device: Atopiclair® Cream cleared under K024367.

4. **Device Description:** PruClair™ non-steroidal cream is a non-sterile, viscous emulsion/formulation, which is presented for both Prescription (requiring a physician diagnosis disease state) and over-the-counter (OTC) use.

INDICATIONS FOR USE- PRESCRIPTION

Under the supervision of a healthcare professional, PruClair™ non-steroidal cream is indicated to manage various types of dermatoses.

INDICATIONS FOR USE- OTC

PruClair™ non-steroidal cream is indicated for minor burns, minor cuts, minor lacerations, and minor irritations.

DIRECTIONS FOR USE- PRESCRITION AND OTC

PruClair™ non-steroidal cream is applied to the affected skin areas 2 to 3 times a day (or as needed), and massage gently into the skin. If the skin is broken, cover PruClair™ nonsteroidal cream with a dressing of choice.

PHYSICAL DESCRIPTION OF DEVICE

PruClair™ cream is an off-white, nonsteroidal cream comprised of Deionized water, Ethylhexyl palmitate, Pentylene glycol, Butyrospermum parkii, Capryloyl glycine, Glyceryl stearate, PEG-100 stearate, Arachidyl glucoside, Behenyl alcohol, Arachidyl alcohol, Bisabolol, Tocopheryl acetate (anti-oxidant), Glycyrrhetinic acid, Carbomer, Ethylhexylglycerin, Piroctone olamine, Sodium hydroxide, Allantoin, DMDM hydantoin, Vitis vinifera, Disodium EDTA, Ascorbyl tetraisopalmitate, Sodium hyaluronate, Propyl gallate, Telmesteine and Butylene glycol.

5. **Intended Use of the Device:** The prescription form of PruClair™ non-steroidal cream requires a physician diagnosis of a disease state and is indicated to manage various types of dermatoses. The OTC version of the device is indicated for minor burns, minor cuts, minor lacerations, and minor irritations.

6. **Summary of Technical Characteristics of Device compared to Predicate Devices:**
The referenced predicate device is also a non-sterile emulsion that is applied to relieve the symptoms of various dermatoses.

7. **Conclusions:** Functional testing has been conducted to assess the safety and efficacy PruClair™ non-steroidal cream and results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Prugen IP Holdings, Inc.
% Robert L. Knechtel, M.D.
EVP and General Counsel
8711 East Pinnacle Peak Road
Suite C201, PMB 225
Scottsdale, Arizona 85255

JUN 2 4 2010

Re: K093156
Trade/Device Name: PRuClair™ non-steroidal cream
Product Code: FRO
Dated: April 15, 2010
Received: April 16, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

(OTC VERSION)

Device Trade Name: PruClair™ non-steroidal cream
510(k) number: K093156

PruClair™ non-steroidal cream is indicated for minor burns, minor cuts, minor lacerations, and minor irritations.

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)

David Krause for M&M

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

510(k) Number K093156

INDICATIONS FOR USE

(PRESCRIPTION VERSION)

Device Trade Name: PruClair™ non-steroidal cream
510(k) number: K093156

Under the supervision of a healthcare professional, PruClair™ non-steroidal cream is indicated to manage various types of dermatoses.

Prescription Use X
(Part 21 CFR 801 Subpart D)

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)