K042955
Page 1 of 1

10.0 510(K) SUMMARY

10.1 Device Name/Sponsor

CUTICOVER™ SKIN BARRIER DEVICE
D & D Holdings, LLC
Contact: Robert Conway
Telephone: 908-534-7714

10.2 Predicate Device/Company Name and Addresses

NUVO Barrier Film (K980117)
EPIKEIA, INC.
500 Sandau, Suite 200
San Antonio, TX 78216-3636

10.3 Description of Device

CUTICOVER™ SKIN is a barrier film of identical formulation to the predicate NUVO Barrier Film device.

10.4 Intended Use

INDICATIONS: "CUTICOVER™ SKIN is a skin barrier for protection against the detrimental effects of moisture, urine, or feces."

10.5 Safety

The formulation is identical to that currently used in the marketed device, NUVO Barrier Film.

10.6 Basis of Substantial Equivalence

The design, composition, indications and packaging are equivalent to similar devices currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2006

D&D Holdings, LLC
% R.G. Conway & Associates Consulting
Services, Inc.
Mr. R.G. Conway
President
Six Edison Road
White House Station, New Jersey 08889

Re: K042955
Trade/Device Name: CUTICOVER™ SKIN Barrier Device
Regulatory Number: 21 CFR 880.5090
Regulatory Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: May 17, 2006
Received: May 19, 2006

Dear Mr. Conway:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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

EXHIBIT 4 - CUTICOVER™ SKIN BARRIER DEVICE - INDICATIONS FOR USE

page 1 of 1

510(K) Number (if known): K042955

Device Name: CUTICOVER™ SKIN Barrier Device

INDICATIONS FOR USE:

Skin barrier for protection against the detrimental effects of moisture, urine, or feces.

Prescription Use_____ -OR- Over-the-Counter Use_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

510(k) Number K042955