

K980117

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Biomedical Development Corporation
500 Sandau, Suite 200
San Antonio, Texas 78216
(210) 308-0636

Contact Person: Ms. Phyllis B. Siegel

Date of Preparation: January 12, 1998

II. DEVICE NAME

Proprietary Name: NUVO™

Common Name: Barrier Film

Classification Name: Liquid Bandage

III. PREDICATE DEVICE

3M™ No Sting Barrier Film, 3M Health Care

IV. DEVICE DESCRIPTION

NUVO™ is a liquid, alcohol-free, film-forming product.

V. INTENDED USE

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

VI. COMPARISON TO PREDICATE DEVICE

NUVO™ Barrier Film is similar in composition, function and design, and has the same intended use as legally marketed liquid bandages, such as the 3M™ No Sting Barrier Film (K955103, 3M Health Care). The biocompatibility of the NUVO™ Barrier Film has been established in an acute dermal toxicity test (rabbit), a primary dermal irritation test (rabbit), a dermal sensitization test (guinea pig), and an *in vitro* cytotoxicity test (USP XXIII). Accordingly, Biomedical Development Corporation has concluded that the NUVO™ Barrier Film is safe and effective for its intended use, and performs as least as well as other liquid bandage devices, such as the 3M™ No Sting Barrier Film.



DEC 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard A. Hamer
Consultant To Biomedical Development Corporation
Richard Hamer Associates, Inc.
6401 Meadows West Drive
Fort Worth, Texas 76132

Re: K980117
Trade Name: NUVO™ Barrier Film
Regulatory Class: I
Product Code: KMF
Dated: November 30, 1998
Received: December 1, 1998

Dear Mr. Hamer:

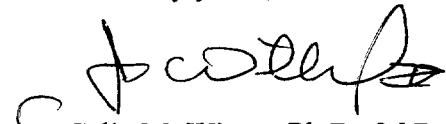
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f) Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K980117

510(k) Number (if known): K980117

Device Name: NUVO™ Barrier Film

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980117

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)