

2/10/99

K984413

510(k) Premarket Notification
K984413 (Previously K963004)
BIONECT® Hydrogel

fidia Pharmaceutical Corporation

February 1, 1999

10. 510(k) SUMMARY

10.1 Summary Information

10.1.1 Submitter's name and address

FIDIA Pharmaceutical Corporation
2000 K Street, NW, Suite 700
Washington, DC 20006

Contact person and telephone number:

Roberto Fiorentini, M.D., President

Telephone: (202) 371-1325

Telefax: (202) 371-1666

Date summary was prepared:

February 1, 1999

10.1.2 Name of the Device

Trade Name: BIONECT® Hydrogel

Common Name: Hyaluronic acid sodium salt hydrogel dressing

Classification Name: Hydrogel Wound and Burn Dressing

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10.1.3 Identification of predicate device to which substantial equivalence is being claimed

BIONECT® Hydrogel is substantially equivalent in function and intended use to the following commercially available non-interactive wound and burn dressings:

- Argidene™ Gel (K945835) (Telios Pharmaceuticals, Inc.)
- Carrasyn™ Hydrogel Wound Dressing (K902345) (Carrington Laboratories, Inc.)
- DuoDERM Hydroactive™ Gel (K830708) (ConvaTec.)

10.1.4 Device description

Explanation of how the device functions: Since it is a hydrogel, BIONECT® Hydrogel provides a moist wound environment that is supportive to wound healing.

Basic scientific concepts that form the basis for the device: BIONECT® Hydrogel was designed to provide a soothing, moist environment that is supportive to wound healing.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: BIONECT® Hydrogel is prepared from sodium hyaluronate and purified water to form a hydrogel dressing. Sodium hyaluronate is a polysaccharide biopolymer that can increase the viscosity of the gel. BIONECT® Hydrogel was designed to provide a soothing, moist environment that is supportive to wound healing.

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10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended

BIONECT[®] Hydrogel provides a moist wound environment that is supportive to wound healing. It is indicated for the dressing and management of minor burns; superficial cuts, lacerations, and abrasions; and minor irritations of the skin. A health care professional may be consulted prior to the first use of this product to determine whether these conditions exist. BIONECT[®] Hydrogel may also be used under the care of a health care professional for wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites), and second degree burns.

These indication statements are not different from the predicate device identified in paragraph (3) of this section.

10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

The technological characteristics of the device such as form, occlusion, conformability, bioburden level, moist wound healing, and appearance in the wound when hydrated are not different from the predicate devices cited.

10.2 Assessment of performance data

In vitro and *in vivo* biocompatibility testing (cytotoxicity, dermal irritation, and dermal sensitization tests) has been performed BIONECT[®] Hydrogel in accordance with FDA

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recommendations.¹ These tests all support the safe use of BIONECT® Hydrogel as a hydrogel temporary dressing in contact with breached or compromised skin.

Clinical experience in approximately 600 patients with various types of ulcers, burns, and surgical wounds in 21 clinical trials (18 controlled) conducted in Europe indicates that BIONECT® Cream is safe for its intended use.

¹ Office of Device Evaluation General Program Memorandum #695-1, International Standard ISO-10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing," dated 1 May 1995.



FEB 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Roberto Fiorentini
President
Fidia Pharmaceutical Corp.
2000 K Street, N.W. – Suite 700
Washington, D.C. 20006

Re: K984262-BIONECT Hydrogel Gauze Pads
K984264-BIONECT Clear Hydrogel
K984266-BIONECT Hydrogel Spray
K984267-BIONECT Hydrogel Foam
K984413-BIONECT Hydrogel

Regulatory Class: Unclassified
Product Code: MGQ
Dated: November 17, 1998
Received: November 17, 1998

Dear Mr. Fiorentini:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are 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 (the Act). You may, therefore, market your devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.
2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. These devices may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the devices and would require a premarket notification submission (21 CFR 807.81).

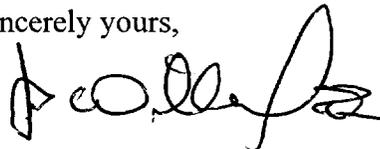
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notifications. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



Celia M. Witten

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

fidia Pharmaceutical Corporation

February 1, 1999

2. INDICATIONS FOR USE

510(k) Number (if known): K984413 (Previously K963004)
K984262 (Previously K973721)
K984267 (Previously K973722)
K984266 (Previously K973725)
K984264 (Previously K973725)

Device Name: BIONECT® Hydrogel
BIONECT® Hydrogel Gauze Pads
BIONECT® Hydrogel Foam
BIONECT® Hydrogel Spray
BIONECT® Clear Hydrogel

Indications for Use:

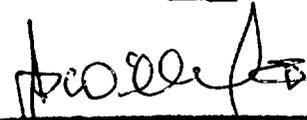
BIONECT® Hydrogel, Gauze Pads, Foam, Spray, and Clear Hydrogel are indicated for the dressing and management of minor burns; superficial cuts, lacerations, and abrasions; and minor irritations of the skin. A health care professional may be consulted prior to the first use of these products to determine whether these conditions exist. BIONECT® Hydrogel, Gauze Pads, Foam, Spray, and Clear Hydrogel may also be used under the care of a health care professional for wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites), and second degree burns.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or

Over-the Counter Use X



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

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K984262, K984264, K984266,
K984267, K984413