

SEP 22 1998

K973725

510(k) Premarket Notification
K973725
BIONECT® Clear Hydrogel
Amendment No. 3

fidia Pharmaceutical Corporation

July 9, 1998

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) 371-9898
Telefax: (202) 371-1666

Date summary was prepared:

July 9, 1998

10.1.2 Name of the Device

Trade Name:	BIONECT® Clear Hydrogel
Common Name:	Hyaluronic acid sodium salt hydrogel dressing
Classification Name:	Hydrogel Wound and Burn Dressing

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

BIONECT® Clear Hydrogel is substantially equivalent in function and intended use to the following cleared non-interactive wound and burn dressing: BIONECT® Hydrogel.

10.1.4 Device description

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

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Basic scientific concepts that form the basis for the device: BIONECT® Clear Hydrogel, since it is a hydrogel dressing, provides 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® Clear Hydrogel is a clear, colorless, hydrogel that 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® Clear Hydrogel, since it is a hydrogel dressing, provides a soothing, moist environment that is supportive to wound healing.

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® Clear Hydrogel is indicated for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns.

These indication statements are not substantially different from the predicate device identified in Section 10.1.3.

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 occlusion, bioburden level, and moist wound healing are not different from the predicate device cited.

10.2 Assessment of performance data

In vitro and in vivo biocompatibility testing (cytotoxicity, dermal irritation, and dermal sensitization tests) has been performed on the bulk solution that impregnates BIONECT® Clear Hydrogel in accordance with FDA recommendations.⁵ These tests all support the safe use of BIONECT® Clear Hydrogel as a hydrogel temporary dressing in contact with breached or compromised skin.

⁵ 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.

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Clinical experience with BIONECT® Hydrogel and BIONECT® Hydrogel Gauze Pads in 22 clinical trials (17 controlled) conducted in Europe in patients with various types of ulcers, burns, and surgical wounds indicates that BIONECT® Clear Hydrogel is safe for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

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

Re: K973721, K973722, K973724 and K973725
Trade Name: Bionect Hydrogel Gauze Pads, Bionect Hydrogel Foam
Bionect Hyrdogel Spray and Bionect Clear Hydrogel
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 1 and July 8, 1998
Received: July 1 and July 9, 1998

Dear Dr. Fiorentini:

We have reviewed your Section 510(k) notification 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 enclosures) 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.

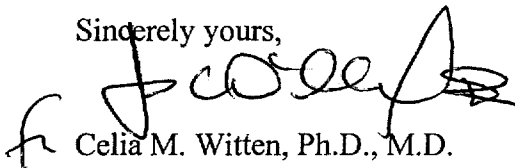
The labeling claims listed above would be considered a major modification in the intended use of the devices and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing 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) they 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 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 devices as described in your 510(k) premarket notification. 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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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

Enclosures

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2. INDICATIONS FOR USE

510(k) Number (if known): K973725

Device Name: BIONECT® Clear Hydrogel

Indications for Use:

BIONECT® Clear Hydrogel is indicated for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns.

V prescription


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973725

Prescription Use X
(Per 21 CFR 801.109)