

FEB 12 1997

510(k) No. K963004  
BIONECT® Cream  
Amendment No. 3

**fidia** Pharmaceutical Corporation

November 26, 1996

**10. 510(k) SUMMARY**

K963004

**10.1 Summary Information**

**10.1.1 Submitter's name and address**

FIDIA Pharmaceutical Corporation  
1401 Eye Street, NW, Suite 900  
Washington, DC 20005

Contact person and telephone number:

Roberto Fiorentini, M.D., President

Telephone: (202) 371-9898

Telefax: (202) 371-1666

Date summary was prepared:

November 26, 1996

**10.1.2 Name of the Device**

Trade Name:	BIONECT® Cream
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® Cream 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: BIONECT® Cream acts to provide a moist wound environment and protect the wound.

Basic scientific concepts that form the basis for the device: BIONECT® Cream was designed to provide a soothing, moist environment for easy application to various types of wounds as a hydrogel dressing.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: BIONECT® Cream 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® Cream was designed to provide a moist wound healing environment.

**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® Cream 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. The dressing is intended to cover a wound or burn on a patient's skin, and protect against abrasion, friction, and desiccation.

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

Biocompatibility testing has been performed as recommended in the "Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing." These tests all support the safe use of BIONECT® Cream 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.