

K982597

510 (k) FIBRACOL* PLUS Collagen Wound Dressing with Alginate

AUG 20 1998

APPENDIX J

510(k) SUMMARY

1. **DATE PREPARED**

1 July, 1998

2. **SUBMITTER**

Johnson & Johnson Medical
A Division of Ethicon Inc.
2500 Arbrook Blvd.
P.O. Box 90130
Arlington, TX 76004-3130

3. **CONTACT PERSON**

Terry James Dagnon
Regulatory Affairs Project Manager
Phone: 817-784-4953
Fax: 817-784-4992 or 817-784-5292

4. **NAME OF THE MEDICAL DEVICE**

Classification Name:	Dressing, Wound
Common/Usual Name:	Topical wound dressing
Proprietary Name:	FIBRACOL* PLUS Collagen Wound Dressing with Alginate

5. **DEVICE CLASSIFICATION**

Product Code/Classification Number:	Unclassified
Regulatory Class:	Unclassified

6. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

FIBRACOL* PLUS Collagen Wound Dressing with Alginate is substantially equivalent and identical in function to FIBRACOL* Collagen-Alginate Dressing (K925548) manufactured by Johnson & Johnson Medical, and SORBSAN Topical Wound Dressing (K881854 Steriseal) & (K914575 Dow B. Hickam) Distributed by Dow Hickam Pharmaceuticals, Inc.

7. **INDICATIONS FOR USE**

FIBRACOL* PLUS Dressing is indicated for the management of exuding wounds including:

- Full thickness & partial thickness wounds
- Pressure Ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns

- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

- *Precautions:*
FIBRACOL PLUS Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause. FIBRACOL PLUS Dressing may be used under compression therapy with healthcare profession supervision.

- *Contraindications:*
FIBRACOL PLUS is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to collagen or alginates.

8. PHYSICAL DESCRIPTION

FIBRACOL* PLUS Collagen Wound Dressing with Alginate is an advanced wound care device composed of collagen and calcium alginate fibers. FIBRACOL PLUS is twice as absorbent as our traditional FIBRACOL* Dressing. Its unique combination of natural biopolymers created by a patented process combines the structural support of collagen and the gel forming properties of alginates into a sterile, soft, absorbent, conformable topical wound dressing. The dressing is manufactured from bovine collagen and medical grade alginate.

The source of collagen is from bovine hide splits from Australia. The hides are from healthy cattle slaughtered under the supervision of a Government appointed Veterinary Officer and subsequently processed further in a controlled clean room in order to avoid the possibility of bovine spongiform encephalopathy (BSE) contamination. The collagen is linked with the calcium alginate using a patented process.

9. BIOCOMPATIBILITY

FIBRACOL PLUS has been demonstrated to be an acceptable topical wound dressing.

The following safety testing was conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices to support the biocompatibility of this product.

- Agar Overlay Assay (L929 Cells)
- Hemolysis (Rabbit RBCs)
- MEM Elution Test
- Muscle Implantation (Rabbits)
- Systemic Injection (Mice)
- Rabbit Pyrogen Assay
- Primary Skin Irritation (Rabbits)
- Guinea Pig Maximization

In taking all the test results on FIBRACOL PLUS as a whole, FIBRACOL PLUS has been demonstrated to be a safe topical wound dressing in accordance with ISO 10993-1.



MAR 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Terry J. Dagnon
Regulatory Affairs Project Manager
Johnson & Johnson Medical, Inc.
2500 Arbrook Blvd.
P.O. Box 90130
Arlington, Texas 76004

Re: K982597
Trade Name: Fibracol Plus Collagen Wound Dressing with Alginate
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 23, 1998
Received: July 24, 1998

Dear Mr. Dagnon:

This letter corrects our substantially equivalent letter of August 20, 1998.

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 (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 and the following limitations:

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

4. This device 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 device and would require a premarket notification submission (21 CFR 807.81).

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 continue 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.

Page 3 – Mr. Terry J. Dagnon

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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

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

510(k) Number : K982597

Applicant: Johnson & Johnson Medical
A Division of Ethicon Inc.
2500 Arbroom Blvd.
Arlington, TX 76004-3130

Device Name: FIBRACOL* PLUS Collagen Wound Dressing with
Alginate (FIBRACOL PLUS)

Indications for Use: FIBRACOL* PLUS Dressing is indicated for the management
of exuding wounds including:

- Full thickness & partial thickness wounds
- Pressure Ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

Precautions:

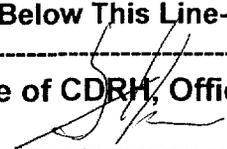
FIBRACOL PLUS Dressing may be used when visible signs of infection are present
in the wound area only when proper medical treatment addresses the underlying
cause. FIBRACOL PLUS Dressing may be used under compression therapy with
healthcare profession supervision.

Contraindications:

FIBRACOL PLUS is not indicated for wounds with active vasculitis, third-degree
burns, or patients with known sensitivity to collagen or alginates.

(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 Devices
510(k) Number K982597

Prescription Use Or Over-The-Counter Use _____
(Per 21 CFR 801.109)