K022995

510(k) Summary

Submitter's Name and Address:

BioCore Medical Technologies, Inc.
11800 Tech Rd. Suite 240
Silver Spring, MD 20904

DEC 0 2 2002

Contact Person, Telephone and Fax Number:

Ajay Kumar
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Date Summary was Prepared:

September 6, 2002

Device Names:

Proprietary Name:	Collatek Hydrogel
Common Name:	Wound dressing
Classification Name:	Wound and burn dressing

Predicate Device:

Trade name:	Woun'Dres Collagen Hydrogel Wound Dressing
Company:	Coloplast Corporation
510(k) number:	K991202
Date Approved:	June 4, 1999

Trade name:	Nu-Gel Wound Dressing
Company:	Johnson and Johnson Medical Inc.
510(k) number:	K983362
Date Approved:	December 16, 1998

Device Description:

Collatek Hydrogel is a sterile wound-dressing from polyacrylic acid and collagen. The dressing encourages healing by maintaining a moist environment at the wound site in the case of dry of lightly exudating wounds. The collagen used in the dressing is from animals born, raised and slaughtered in the USA.

Basis for Substantial Equivalence:

1. Indications for Use

Collatek Hydrogel will be used to manage full thickness and partial thickness wounds with moderate to heavy exudate. Collatek Hydrogel is intended for use on dry, light and moderately exudating of the following types: first and second degree burns, severe sunburns, superficial injuries, abrasions, cuts, surgical wounds, pressure ulcers, venous stasis ulcers, ulcers caused by mixed etiologies, diabetic ulcers, donor sites and grafts.
Woun'Dres is indicated for partial and full thickness wounds including pressure ulcers, diabetic ulcers, lower extremity ulcers including venous arterial and mixed etiology, surgical wounds, first and second degree burns and abrasions. Nu-Gel is indicated for first and second degree burns, severe sunburns, superficial injuries, radiation

burns, pressure ulcers stage I-IV, lower extremity ulcers, venous ulcers, arterial ulcers, ulcers of mixed etiology, diabetic ulcers, donor sites and grafts. Therefore, Collatek Hydrogel 's indications for use are comparable to the predicate devices (Woun'Dres and Nu-Gel Wound Dressing).

2. Technological Characteristics

Collatek Hydrogel is designed to create a favorable environment at the wound site by providing a moist environment in the case of dry or light to moderately exudating wounds. Nu-Gel provides a moist environment by protecting against dehydration and absorbing excess exudates. Woun'Dres is a hydrogel dressing for providing a moist environment. Therefore, Collatek Hydrogel is similar in technological characteristics to the predicate devices (Woun'Dres and Nu-Gel Wound Dressing).

3. Materials

Collatek Hydrogel contains polyacrylic acid (Trade name: Carbomer) and collagen as primary components. Woun'Dres is made from collagen and Allantoin. Nu-Gel consists of polyvinyl pyrrolidone. The polymers in these dressings are to use to provide a hydrogel for maintaining a moist environment. Therefore, Collatek Hydrogel is similar to the predicate devices (Woun'Dres and Nu-Gel Wound Dressing) with respect to materials of construction.

4. Safety

Biocompatibility testing has confirmed that Collatek Hydrogel meets requirements as stated by the FDA regulations in Blue Book Memorandum G95-1. Biocompatibility tests were in accordance with GLP. Woun'Dres and Nu-Gel Wound Dressing both passed biocompatibility tests.

5. Sterility and Packaging

Collatek will be packaged as a sterile dressing.

Conclusion

Collatek Hydrogel is similar in design, function, materials and intended use and is therefore substantially equivalent to the commercially available predicate devices: Woun'Dres and Nu-Gel Wound Dressing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

BioCore Medical Technologies, Inc.
Ajay Kumar
VP of Operations
11800 Tech Road, Suite 240
Silver Spring, Maryland 20904

Re: K022995
Trade/Device Name: Collatek Hydrogel
Regulation Name: Wound and burn dressing, hydrogel
Regulatory Class: Unclassified
Product Code: MGQ
Dated: September 6, 2002
Received: September 9, 2002

Dear Mr. Kumar:

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 application (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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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 begin 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): K022995

Device Name: Collatek Hydrogel

Indications for Use:
Collatek is indicated for dry, light and moderately exudating partial and full thickness wounds such as:

- First and second degree burns
- Severe sunburns
- Superficial injuries, cuts, abrasions and surgical wounds

Collatek Hydrogel may be used under clinical guidance in the management of the following types of dry, light and moderately exudating partial and full thickness wounds:

- Pressure (stage I-IV) and venous stasis ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Donor sites and grafts

Precautions:

- Collatek Hydrogel is not recommended for persons sensitive to bovine products
- Collatek is not recommended for third degree burns

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022995

Prescription Use_____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)