OCT 2 5 2001

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BioCore Medical Technologies, Inc.

State-of-the-Art Biomaterials Technologists

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Silver Spring, Maryland 20904
U.S.A.

510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is: K012997

Submitter's Name and Address:

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

Contact Person, Telephone and Fax Number:

Ajay Kumar, VP of Operations
Phone: (301) 625-6818
Fax: (301) 625-6819

Date the Summary was Prepared:

September 19, 2001

Device Names:

Proprietary Name:	Collatek® Foam
Common Name:	collagen/foam wound dressing
Classification Name:	occlusive, wound and burn dressing

Predicate Device:

Marketed name:	VigiFOAM®
Marketing Company:	C.R. Bard, Inc.
510(k) Trade name:	Hydrasorb™
510(k) Company:	Avitar Technologies Inc.
Trade name:	SkinTemp®
Company:	BioCore Medical Technologies, Inc.

Kollagen™

Device Description:

Collatek® Foam is a sterile, disposable, single use, wound-dressing device for the management of dermal lesions and injuries. It is to be used to manage full and partial thickness wounds with moderate to heavy exudate.

Collatek® Foam is composed of two separate layers: a collagen matrix layer and a medical grade foam layer. Collatek® Foam's collagen matrix layer is made from insoluble fibrous type I bovine collagen derived from cowhide. Collatek® Foam's foam layer is a medical grade polyurethane foam. Collatek® Foam will be initially available in a 4"x 4" size pad, additional sizes may be introduced at a later time.

Basis for Substantial Equivalence:

1. Indications for Use

Collatek® Foam will be used to manage full and partial thickness wounds with moderate to heavy exudate. Collatek® Foam is intended for use on these types of wounds: pressure ulcers (stages I-IV), venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first and second degree burns, donor sites and other bleeding or secreting dermal lesions/injuries.

Collatek® Foam is comparable in indications for use as the commercially available predicate device (VigiFOAM®, SkinTemp®).

2. Instructions for Use

Collatek® Foam's manner of wound dressing is intended to be similar to that of other wound care dressings. First, cleanse the wound. Second, apply medication to the wound as indicated. Third, apply Collatek® Foam to the wound surface. Lastly, Cover with absorbent non-stick dressing and change dressing as needed in accordance with labeling instructions.

Collatek® Foam is comparable in instructions for use as the commercially available predicate devices (VigiFOAM® and SkinTemp®).

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3. Technological Characteristics

Collatek® Foam is composed of two separated layers bonded together to form a single wound care pad. Collatek® Foam's wound-contacting surface is a fibrous type I collagen layer. Collagen protects the wound bed and newly formed granulation tissue by formation of an occlusive gelatinous barrier

Collatek® Foam's absorbent backing layer is a medical grade polyurethane foam. Collatek® Foam's collagen layer can absorb many times its weight in liquid while the outer foam layer aids in liquid evaporation; this gives Collatek® Foam excellent fluid handling properties.

Collatek® Foam is similar in design as compared to the commercially available predicate devices (VigiFOAM® and SkinTemp®).

4. Materials

The material used for Collatek® Foam's collagen matrix includes fibrous Type I bovine collagen derived from cowhide. The material used for Collatek® Foam's foam layer is a medical grade polyurethane foam.

The constituents of Collatek® are the same as the constituents of the commercially available predicate devices (VigiFOAM® and SkinTemp®).

5. Safety

Biocompatibility testing has confirmed that Collatek® meets or exceeds all biocompatibility testing requirement as stated in the FDA Blue Book Memorandum G95-1 and in ISO 10993. Biocompatibility tests were performed by North American Science Associates, Inc. (NAmSA) in accordance with GLP. Biocompatibility data has shown that Collatek® is safe for use as a medical device for wound care management, the biocompatibility results are shown in section K.

6. Sterility and Packaging

Collatek® Foam will be packaged in a single use, disposable Tyvek® pouch. Collatek® Foam will be sterilized using an electron beam to irradiate the Tyvek® pouch and its contents. Collatek® Foam will be sterilized to a SAL index of 10^{-6}. The sterility of Collatek® Foam will be ensured by validation in accordance with ANSI/AAMI/ISO 11137-1994.

Conclusion

With respect to design, function, materials and intended use, Collatek Foam dressing is similar in properties and characteristics with the commercially available predicate devices: VigiFOAM (C.R. Bard, Inc.) and SkinTemp (BioCore Medical Technologies, Inc.). We therefore submit that Collatek foam dressing is substantially equivalent to VigiFOAM and SkinTemp. Table I-2.1.2 provides a side-by-side comparison for a basis of substantial equivalence for Collatek Foam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2001

Mr. Ajay Kumar
Vice President of Operations
BioCore Medical Technologies, Inc.
11800 Tech Road
Suite #240
Silver Spring, Maryland 20904

Re: K012997
Trade Name: Collatek Foam
Regulatory Class: Unclassified
Product Code: MGP
Received: September 6, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

Susan Walker, MD

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): K012997

Device Name: Collatek Foam

Indications for Use:

Collatek Foam may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- Ist and 2nd degree burns
- Cuts, abrasions and surgical wounds

Contraindications:

Collatek Foam should not be used on persons sensitive to bovine products.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

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

510(k) Number #K012997