K040283

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JUL 2 2 2005

BIOPAD®
TRADITIONAL 510(K) PREMARKET NOTIFICATION-SUMMARY

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary for BIOPAD® is being submitted in accordance with the requirements of 21 CFR Part 807.92(c)

DATE OF SUMMARY [807.92(a)(1)]
November 13, 2004

SUBMITTER NAME/ADDRESS [807.92(a)(1)]
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CONTACT PERSON [807.92(a)(1)]
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DEVICE INFORMATION [807.92(a)(2)]

Proprietary name	BIOPAD®
Other proprietary names and laboratory codes	*Gelfix, Condress, Proteita, Stimtes, TN 921, BG PRG, EU 10102: all these brand names identify the same collagen pad undergoing the same manufacturing process, manufactured in the same facility and with the same identical composition and dosage.*
Trade name	BIOPAD®
Common name	Collagen pad, or patch, or sheet, or sponge
Classification name	Wound dressing
Regulatory Class	Unclassified

SUBSTANTIAL EQUIVALENCE [807.92(a)(3)]
BIOPAD® is substantially equivalent in material, function, intended use and performance to the following commercially available wound dressings, that obtained marketing approvals under SE 510(k) Premarket Notification process, and are currently marketed in U.S. for the management of bleedings and wounds, i.e. :

PREDICATE DEVICE	510(K)	MANUFACTURER
HeliDerm collagen wound dressing	K990086	Integra LifeScience Corporation
Fibracol Plus collagen wound dressing with alginate	K982597	Johnson & Johnson Medical
SIS Wound Dressing II	K993490	Cook Biotech Inc.

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BIOPAD®
TRADITIONAL 510(K) PREMARKET NOTIFICATION-SUMMARY

DEVICE DESCRIPTION [807.92(a)(4)]

BIOPAD® is a wound dressing for topical use to control minor bleedings and for the management of any kind of ulcer and skin lesion to help wound closure.

BIOPAD® is a sponge shaped device, constituted exclusively by lyophilized type 1 native heterologous collagen extracted from horse flexor tendon.

When applied to a wound, BIOPAD® constitutes a barrier for wound against exogenous infective agents.

BIOPAD® is the ideal first-aid means to control minor bleeding.

The device may be used by healthcare professionals.

BIOPAD® is supplied sterile and for one-time use only.

INDICATIONS FOR USE

BIOPAD® is a collagen wound dressing intended for control of minor bleeding, and for the local management of moderately to heavy exuding wounds including:

- Pressure sores,
- Donor sites and other bleeding surfaces,
- Dehisced surgical incisions,
- Draining wounds,
- Lacerations,
- Venous stasis ulcers,
- Diabetic ulcers,
- Partial and full thickness wounds,
- Post-laser surgery,
- Podiatric, and
- Surgical and traumatic wound.

The product is supplied sterile and for one-time use.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Precautions

It is important to apply correctly BIOPAD® previously cleansing the wound[1], eventually removing the purulent material or necrotic tissues.

BIOPAD® is not intended to replace ligation in case of heavy bleeding.

Side Effects

No side or adverse effects have ever been reported.

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Contraindications

Do not use in patients with known family history of auto-immune diseases, history of anaphylactoid reactions or known hypersensitivity to collagen, both topical and injectable, or in subjects undergoing desensitization therapy to meat products.

TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

BIOPAD® is designed to protect the wounded area, absorbing wound exudates and controlling minor bleedings, thus representing an effective and safe mean for the management of wounds.

STERILITY

BIOPAD® is available in single sterile package.
It is gamma rays irradiated at a validated dose level that proved to be non-denaturing for the collagen protein, assuring a SAL level better than 1 on 10^{-6}.

SAFETY AND EFFECTIVENESS

a) ANIMAL AND LABORATORY TESTINGS [807.92(b)(1)]
A biocompatibility assessment according to UNI EN ISO 10993 Part 10 confirmed BIOPAD® to be non-cytotoxic, non-irritant and non sensitizing.

An acute skin irritation and a 28 days repeated skin irritation study, performed to UNI EN ISO 10993 Parts 5 and 10 demonstrated BIOPAD® to be non-irritant even at repeated applications.

A reverse mutation study (Ames Test) performed according to UNI EN ISO 10993 Part 3 confirmed BIOPAD® to be non-mutagenic.

The bacterial endotoxins tests (LAL) performed according to USP 27 confirmed BIOPAD® to be non pyrogenic.

b) CLINICAL TRIALS AND EXPERIENCE [807.92(b)(2)]
BIOPAD® demonstrated its efficacy in clinical applications to control minor bleeding and in the management of wounds.

CONCLUSIONS [807.92(b)(3)]
Biocompatibility studies have demonstrated BIOPAD® to be non-toxic, non irritating, non-sensitizing, non-cytotoxic and non pyrogenic.

The manufacturing and sterilization processes, performed under QA and GMP, as well as the scientific evidence of the several studies made on the product provide a reasonable assurance that BIOPAD® is safe and effective for the proposed use and that, with respect to materials, function, intended use and performance it is substantially equivalent to the predicate devices listed above and to the requirements for 510 (k) Premarket Notification as per 21 CFR Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2005

Euroresearch S.R.L.
c/o Mr. E. J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K040283
Trade/Device Name: BIOPAD
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2005
Received: April 25, 2005

Dear Mr. Smith:

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040283

Indications for Use

510(k) Number (if known): K040283

Device Name: BIOPAD

Indications for Use:

BIOPAD® is a collagen wound dressing intended for the control of minor bleeding, and for the local management of moderately to heavy exuding wounds including:

- pressure ulcers,
- venous stasis ulcers,
- diabetic ulcers,
- partial and full thickness wounds,
- surgical and traumatic wounds,
- donor sites and other bleeding surface wounds
- dehisced surgical incisions
- draining wounds
- lacerations
- podiatric
- post-laser surgery

The product is supplied sterile and for one-time-use only.

Prescription Use
___X___
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K040283

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