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AUG - 9 2004

K030774

(letterhead)

510(k) Summary

STIMULEN™ COLLAGEN

Safety and effectiveness information submitted in accordance with 21CFR § 807

Submitter/
Contact Person: Edward I. Stout, President
Southwest Technologies, Inc.
1746 Levee Road
N. Kansas City, MO. 64116

Telephone: (816) 221-2442
Fax: (816) 221-3995
email: swtech@birch.net

Date prepared: July 1, 2004

Device Name and Classification

Proprietary Name: Stimulen™ Collagen
Common Name: Wound Dressing
Classification Name:
Classification:

Manufacturer

Southwest Technologies, Inc.
1746 Levee Road
N. Kansas City, MO. 64116

Substantial Equivalence Claim

Medifil™ by BioCore (K 910944)
hyCure™ by Hymed Group (K955506)
Collatek™ by BioCore (K012990)
HeliDerm™ by Integra (K990086)

Device Description

Stimulen™ Collagen is a sterile primary single use dressing comprised of soluble modified bovine collagen base. The Stimulen™ collagen is soluble in the wound fluid and supplied as a powder or gel or sheet.

Intended Use

Stimulen™ Collagen is indicated for the management of wounds including full and partial thickness wounds, pressure ulcers (stages I-IV), venous stasis ulcers, diabetic ulcers, partial thickness burns, acute wounds, abrasions, traumatic wounds healing by secondary intention, donor sites and other surface wounds.

Comparison to Predicate Devices

Device Name	Stimulen™	Medifil™	HyCure™	Collatek™	HeliDerm™
Manufacturer	Southwest Tech.	BioCore	Hymed Group	BioCore	Integra
Indications For use	Prolonged use in The management of Full and partial thick-Ness wounds.	Used to manage Full and partial Thickness wounds with minimal to Heavy exudate.	Used in the Management of chronic and Acute wounds.	Used to manage full and partial Thickness wounds With moderate to Heavy exudate.	Used in the Management of Moderately to Heavily exudating Wounds and the Control of minor Bleeding.
Material	Soluble modified Collagen	Type I Collagen	96% derived from Type I Collagen	Type I Collagen	Type I Collagen
Collagen Source	Bovine	Bovine	Bovine Flexor Tendon	Bovine	Bovine Flexor Tendon
Biodegradable	Yes	Yes	Yes	Yes	Yes
Bio-Compatibility	Yes	Yes	Yes	Yes	Yes
Sterile	Yes	Yes	Yes	Yes	Yes

Technological characteristics:

I. Stimulen™ Modified Collagen is a dry particulate powder. which will dissolve in warm wound exudate

II. Stimulen is also supplied as an amorphous gel.

III. Stimulen is also supplied as a gel sheet.

Safety

Chemical analysis indicated the amino acid composition are essentially equivalent to the HyCure collagen. Elemental metal analysis also shows the similar levels of trace metals.
Bioburden analysis of the non-sterile Stimulen showed low levels of contamination, less than 100 c.f.u. Biocompatibility tests, Primary Skin Irritation Test, Acute Systemic Injection Test, Intracutaneous Test demonstrated the Stimulen collagen to be non-toxic and non-irritating.

Sterility and Packaging

Stimulen™ Modified Collagen will be packaged in a suitable container(vial, bottle, pouch). The container and contents will be sterilized at an SAL of 10^{-6} in accordance with AAMI/ISO 11137.

Conclusion

Stimulen™ Modified Collagen is essentially equivalent in design, function, source of substrate materials, and indicated use, to the commercially available predicate devices, and therefore meets the requirements as defined in 21 CFR § 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Dr. Edward I. Stout
President
Southwest Technologies, Inc.
1746 Levee Road
N. Kansas City, Missouri 64116

Re: K030774
Trade/Device Name: Stimulen™ Collagen
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 1, 2004
Received: July 6, 2004

Dear Dr. Stout:

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. 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K030774

Device Name: STIMULEN COLLAGEN

Indications For Use:

Stimulen™ Collagen is indicated for prolonged use (24 hr to 30 days) in the management of wounds including:

- full and partial thickness wounds
- pressure ulcers (stages I-IV)
- venous stasis ulcers
- diabetic ulcers
- partial thickness burns
- acute wounds
- abrasions
- traumatic wounds healing by secondary intention
- donor sites and other surface wounds

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 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 K030774