K040314

AUG 1 2 2004

510(k) SUMMARY

Applicant Name and Address: ENCOLL Corp.
4576 Enterprise St., Fremont, CA-94538

Contact Person: S. Gunasekaran, PhD

Date of Summary: 1-10-2004

Device Common Name: Dressing, wound, Collagen

Device Trade Name: HELICOLL

Device Classification Name: **Collagen Wound Dressing**
Unclassified

Product Code: **KGN**

Substantial Equivalence Statement:

Helicoll is a collagen wound dressing device similar to predicate collagen-based devices that are previously approved by the agency and allowed for marketing towards the management of wounds.

Such predicate devices are listed below:

SkinTemp® Kollagen Particles, K913023

Medifil® Kollagen Particles, K910944

Collatek® Powder, KO12990

HeliDermTM Collagen Wound Dressing, K990086

hyCure® Advanced Collagen Wound Care, US5506

Fibracol™ Collagen-Alginate Dressing, K925548

Fibracol Plus™ Collagen-Alginate Dressing, K982597

CollagenDressing, K03721

SIS Wound Dressing II, by Cook Biotech, K993948

The proposed device is another collagen wound dressing that is quite similar with respect to the indications for use, the major material and the physical construction to the above devices in terms of the substantial equivalency under the 510(k) regulations.

Description of the Device

Helicoll is a translucent, off-white, semi-occlusive, self-adhering and ready to use pre-sterilized Type-1 Collagen Sheet for Second-degree Burn, Chronic Ulcers and other topical Wound Managements. Helicoll is flexible with moderate tackiness.

Helicoll is a reconstituted collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins (refer to the US Patents below:)

1. 6,548,077(2003) Titled: Purifying type I collagen using two papain treatments and reducing and delipidation agents.
2. 6,127,143(2000) Titled: Preparation of purified and biocompatible collagen using two proteolytic enzyme treatments and a reducing agent
3. 5,814,328(1998) Titled: Preparation of collagen using papain and a reducing agent.

Helicoll maintains a physiologically moist microenvironment at the wound surface. This device is intended for one time use only.

Indications or the Intended Uses of the Device:

Helicoll is intended for the topical wound management that includes:

- Partial and full-thickness wounds.
- Pressure ulcers.
- Venous ulcers.
- Chronic vascular ulcers.
- Diabetic ulcers.
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence

Summary Comparison of Technical Characteristics

Collagen Topical Wound Dressing and its predicates have similar technological characteristics. In particular, the Collagen Topical Wound Dressing and its predicates are similar with respect to intended use, material, form, shape, etc.

Safety and Efficacy

Collagen Topical Wound Dressing has been evaluated by the following tests to monitor its safety and biocompatibility.

1) In vitro Hemolysis (Rabbit RBCs)
2) Cytotoxicity – Agarose Overlay

3) Intracutaneous Toxicity (Rabbits)

4) Dermal Sensitization – Maximization (Guinea Pigs)

5) Muscle Implantation (Rabbits – 1 week)

6) Acute Systemic Toxicity (Mice)

7) USP Pyrogenicity (Rabbits)

8) Mutagenecity (AMES) Test

9) Muscle Implantation (Rabbits – 13 weeks)

10) Embryonic Cytotoxicity

Additional tests conducted are:

Acute Oral Toxicity (Mice)

Systemic Antigenecity (Guinea Pigs)

Skin irritation (Rabbits)

LAL Chromogenic Assay

Heavy Metal analysis

(Please find the detailed protocol and the results in the Appendix of the original submission)

Helicoll has passed all applicable testing for the biological evaluation of medical devices.

Conclusion

The results of the ***in vitro*** product characterization studies and biocompatibility studies indicate that Helicoll, the Collagen Topical Wound Dressing, is safe and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Subramanian Gunasekaran, Ph.D.
President
Encoll Corporation
5686 Geranium Court
Newark, California 94560

Re: K040314
Trade/Device Name: Helicoll
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 28, 2004
Received: June 29, 2004

Dear Dr. Gunasekaran:

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,

Miriam C. Provost

for 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): K 040314

Device Name: HELICOLL

Indications For Use:

The Healicoll Topical Collagen Wound Dressing is intended for the topical wound management that includes:

- Partial and full-thickness wounds.
- Pressure ulcers.
- Venous ulcers.
- Chronic vascular ulcers.
- Diabetic ulcers.
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears),
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number K040314

[redacted]