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K990086

HeliDerm™ *Collagen Wound Dressing*

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name and address:

Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, NJ 08536

Contact person and telephone number:

Judith E. O'Grady
Senior Vice President, Regulatory Affairs, Quality Assurance and Clinical Research
(609) 275-0500

Date Summary was prepared:

January 8, 1999

Name of the device:

Proprietary Name:	HeliDerm™ *Collagen Wound Dressing*
Common Name:	Topical Wound Dressing
Classification Name:	Dressing, Class I, 21CFR 878.4060

Substantial Equivalence:

HeliDerm™ is substantially equivalent in function, form and intended use to other commercially available non-interactive wound and burn dressings including:

hycure® manufactured for Southwest Technologies, Inc.
Fibracol manufactured by Johnson & Johnson Medical, Inc.
KALTOSTAT® WOUND PACKING manufactured for Convatec, a Bristol-Myers Squibb Company
Chronicure manufactured by ABS LifeSciences an Integra LifeSciences Company
VitaChoice manufactured by Vitaphore Corporation an Integra LifeSciences Company

Device Description:

HeliDerm™ *Collagen Wound Dressing* is a white, absorbent collagen in microfibrillar form for the management of moderately to heavily exudating wounds, and the control of minor bleeding. It provides a physiologically favorable environment that encourages wound healing. When interacting with the wound fluid, it immediately begins to absorb the exudate which may impair tissue regeneration. HeliDerm™ is made from natural materials that contain the proteins that constitute the major building blocks of normal skin and connective tissue. HeliDerm™ protects the wound bed and delicate new tissue. In normal healing wounds, collagen is produced in large quantities by fibroblasts that are recruited to the injured site during the proliferation phase of healing. Collagen and collagen materials may augment fibroblast recruitment and endogenoous collagen production which may encourage and enhance this phase for chronic wounds. The intended use is comparable to absorbent gauze, medical fibers, powdered sponges, and absorbent beads, in that its primary function is to

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absorb wound exudate. HeliDerm™ is purified bovine flexor tendon collagen. HeliDerm™ is to be applied directly to the secreting wound. HeliDerm™ can absorb greater than 10 ml of fluid per gram and will absorb wound fluids, bacteria, protein products and other microscopic debris that may retard the healing process.

In addition, HeliDerm™, being comprised of microfibrillar collagen, is an excellent hemostatic agent which can be used to control minor bleeding. HeliDerm™ is supplied sterile, nonpyrogenic, and for single use in a single blister package.

Statement of intended use:

HeliDerm™ *Collagen Wound Dressing* is indicated for the management of moderately to heavily exudating wounds, and to control minor bleeding.

HeliDerm™ may be used for the management of exudating wounds such as:

- PRESSURE ULCERS
- VENOUS STASIS ULCERS
- DIABETIC ULCERS
- ACUTE WOUNDS, for example trauma and surgical wounds
- PARTIAL-THICKNESS BURNS

Comparison of technological characteristics to predicate devices:

A table comparing characteristics of HeliDerm™ Collagen Wound Dressing and the predicate devices is provided in Table 2.

Safety

Biocompatibility studies have demonstrated HeliDerm™ to be: non-cytotoxic, non-pyrogenic, non-irritating, and non-sensitizing. The following studies were conducted:

Cytotoxicity
Primary Skin Irritation
Pyrogenicity
Sensitization/Maximization
Subcutaneous Implant
Systemic toxicity
Hemolysis
Intracutaneous Toxicity

The HeliDerm™ manufacturing process complies with the United States Food and Drug Administration and European Standards for animal tissue sourcing and viral inactivation.

Conclusion

HeliDerm™ *Collagen Wound Dressing* is a member of a family of collagen products manufactured by Integra LifeSciences Corporation with an extensive and established seventeen-year history of safety and effectiveness. Collagen has a primary role in all phases of wound healing, making it an effective agent for managing the treatment of wounds. Having the natural property of platelet binding, collagen is optimal for hemostasis. HeliDerm™, being comprised of Type I collagen and having been designed to absorb fluids will aid in the management of exudating wounds and control minor bleeding.

HeliDerm™ *Collagen Wound Dressing* is substantially equivalent to the predicate devices delineated in this submission and the requirements for a Premarket Notification 510(k) as defined in CFR 21, Part 807.

Table 2: Substantial Equivalence Comparison Chart

Feature	HeliDerm™ *Collagen Wound Dressing*	hycure® *Advanced Collagen Woundcare*	KALTOSTAT® WOUND PACKING *Calcium-Sodium Alginate Fiber*	VitaChoice® *Wound Dressing*	Chronicure™ *Absorptive Wound Dressing*	Fibracol™ *Collagen-Alginate Dressing*
Manufacturer	Integra LifeSciences Corporation	Southwest Technologies, Inc.	Convatec, a Bristol-Myers Squibb Company	Vitaphore Corp., an Integra LifeSciences Company	ABS LifeSciences, Inc., an Integra LifeSciences Co.	Johnson & Johnson Medical, Inc.
Indications for Use	Used in the management of moderately to heavily exudating wounds and the control of minor bleeding	Used for the management of chronic and acute wounds, and skin ulcers	Used as an external wound dressing designed to absorb exudate, control minor bleeding and protect the wound from contamination.	Used in the management of dermal ulcers and chronic wounds.	Used as an aid in the management of chronic wounds and ulcers of the skin.	Used as an aid in the management of chronic wounds and ulcers of the skin.
Materials	Type I Collagen	96% Type I Collagen	Calcium-sodium alginate	Collagen	Collagen	Collagen/Calcium Alginate
Collagen Source	Bovine Flexor Tendon	Bovine Flexor Tendon	Not applicable	Bovine Flexor Tendon	Avian	Bovine hide
Biodegradable	Yes	Yes	Yes	Yes	Yes	Yes
Bio-compatibility	Yes - Animal Studies	Yes - Animal Studies	Yes	Yes-Animal Studies	Yes - Animal Studies	Yes - Animal Studies
Non-Pyrogenic	Yes	Yes	Not claimed	Yes	Not Claimed	Not Claimed
Sterile	Yes - Ethylene Oxide	Yes	Yes	Yes	Yes - γ radiation	Yes - γ radiation
Sizes	0.5 gram, 1.0 gram	1.0 gram	Not listed	Not manufactured presently	1 gram individual packets and 30 gram bottles	2 x 2 inches x 3 mm to 10 x 10 inches x 3 mm
Storage Conditions	Room temperature	Room temperature	Cool, dry place	Room temperature	Room temperature.	None stated

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Ms. Judith E. O'Grady, RN, MSN
Senior Vice President
Regulatory Affairs, Quality Assurance and Clinical Research
Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

Re: K990086
Trade Name: HeliDerm™ Collagen Wound Dressing
Regulatory Class: Unclassifed
Product Code: FRO
Dated: January 8, 1999
Received: January 11, 1999

Dear Ms. O'Grady:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

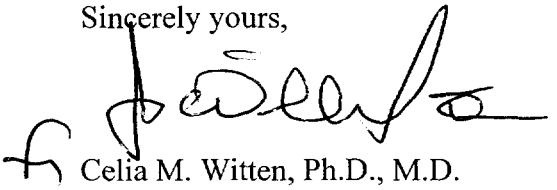
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE

Indications

510(k) Number:

Device Name: HeliDerm™ ***Collagen Wound Dressing***

Indications for Use:

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HeliDerm™ may be used for the management of exudating wounds such as:

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(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 _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990086