

K983394

NOV 3 1998

APPENDIX H

510(k) SUMMARY

1. DATE PREPARED

October 13, 1998

2. SUBMITTER

Johnson & Johnson Medical
Division of Ethicon Inc.
2500 Arbrook Blvd.
P.O. Box 90130
Arlington, TX 76004-3130

3. CONTACT PERSON

Terry James Dagnon
Regulatory Affairs Project Manager
Phone: 817-784-4953
Fax: 817-784-4992 or 817-784-5292

4. NAME OF THE MEDICAL DEVICE

Classification Name:	Dressing, Wound
Common/Usual Name:	Topical wound dressing
Proprietary Name:	TIELLE* Hydropolymer Dressing

5. DEVICE CLASSIFICATION

Product Code/Classification Number:	Unclassified
Regulatory Class:	Unclassified

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

TIELLE* Hydropolymer Dressing is substantially equivalent and identical in function to DuoDERM* CGF Control Gel Formula Border Dressing (K973688) manufactured by ConvaTec - A Division of E.R. Squibb & Sons, Inc.

7. INDICATIONS FOR USE

TIELLE* Dressing is indicated for the management of chronic and acute, low to moderately exuding, partial and full thickness wounds including:

- Superficial wounds
 1. Minor abrasions
 2. Skin tears
 3. Second degree burns

TIELLE* Hydropolymer Dressing should be used under health care professional direction for the following indications:

- Pressure ulcers
- Lower extremity ulcers
 1. Venous
 2. Arterial
 3. Mixed etiology
- Diabetic ulcers

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- Donor sites

TIELLE Dressing is suitable for use under compression bandaging.

PRECAUTIONS

TIELLE Dressing is not indicated for use on the following:

- Third degree burns
- Lesions with active vasculitis

TIELLE Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause.

8. PHYSICAL DESCRIPTION

TIELLE* Hydropolymer Dressing is an exudate handling system for low to moderately exuding wounds. The island dressing maintains a moist environment that supports the wound healing process and allows granulation to proceed under optimum conditions. During use the absorbent island gently expands as it takes up exudate. It allows the wound to remain moist which causes autolytic debridement to occur. This may initially increase lesion size, which is normal and to be expected prior to wound granulation.

9. BIOCOMPATIBILITY

The following safety testing was conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices to support the Biocompatibility of this product.

Adhesive Coated Water Resistant Permeable Polyurethane Backing

PRECLINICAL Testing Results	
Five Day Repeated Skin Irritation	Non-irritant
Skin Sensitization Guinea-Pig (Buehler)	Non-sensitizer
Cytotoxicity	Non-cytotoxic

Non-Woven Wicking Layer

PRECLINICAL Testing Results Appendix D	
Cotton pellet granuloma test of Meir, Schuler and Desaulles (1950).	Non-Hazardous
Mammalian blood pressure	Non-Hazardous
Rabbit Intracutaneous Irritation Test	Non-irritant
Rabbit Optic Mucosa Irritation Test	Mild effects of Hot extract only
Guinea pig dermal sensitisation test	Non-sensitizer
Steam vs. Irradiated Sterilization Toxicology Wicking Layer	
Subcutaneous pellet implantation in the rat	No increased risk if sterilized via radiation in place of steam
Effect of Injection of hot water derived residue on the cat blood pressure	No increased risk if sterilized via radiation in place of steam
Rabbit Intra-cutaneous Irritation Test	No increased risk if sterilized via radiation in place of steam
Rabbit Optic Mucosa Irritation Test	No increased risk if sterilized via radiation in place of steam

Absorbent Polyurethane Wound Contact Layer (Central Island)

Safety / Toxicity Testing	
Hemolysis (Rabbit RBCs)	Non-hemolytic
Primary Skin Irritation (Rabbits)	Non-irritant
Acute Oral Toxicity	Non-cytotoxic
Intramuscular Injection Test	Non-cytotoxic
Kligman Maximization Test	Non-sensitizer
Systemic Injection (Mice)	Non-cytotoxicity
MEM Elution Test	Non-cytotoxic
Agar Diffusion Test	Non-Cytotoxic
Ames Assay	Non-mutagenic
L5178Y TK+/- Mouse Lymphoma Mutagenesis Assay	Non-mutagenic
Rat Oral LD ₅₀	LD ₅₀ > than 40g/kg
Rabbit Dermal LD ₅₀	LD ₅₀ for B-15J found to be > 5g/kg
Rabbit Dermal Irritancy (Draize)	Non-irritating
Rabbit Eye Irritation	Non-irritating
Human Repeat Insult Patch Test	Non-irritating & Non-sensitising
Cytotoxicity Test (Agar Overlay)	Non-cytotoxic using L929 mammalian cells



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Terry James Dagnon
Regulatory Affairs Project Manager
Johnson & Johnson Medical
Division of Ethicon Inc.
2500 Arbrook Boulevard
Arlington, Texas 76004-3130

Re: K983394
Trade Name: TIELLE* Hydropolymer Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: September 21, 1998
Received: September 25, 1998

Dear Mr. Dagnon:

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

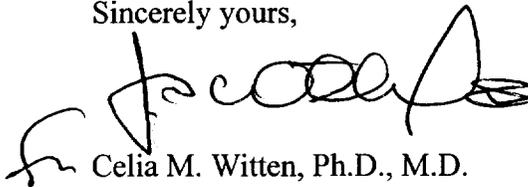
misbranding and adulteration.

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

510 (k) TIELLE* Hydropolymer Dressing
Diabetic Ulcer Submission

510(k) Number : K983394

Applicant: Johnson & Johnson Medical
Division of Ethicon Inc.
2500 Arbrook Blvd.
Arlington, TX 76004-3130

Device Name: TIELLE* Hydropolymer Dressing

Indications for Use:

TIELLE* Hydropolymer Dressing is an exudate handling system intended for low to moderately exuding wounds. The island dressing maintains a moist wound environment. A moist wound environment supports the wound healing process by encouraging autolytic debridement thus enabling granulation to proceed under optimum conditions. During use the absorbent island gently expands as it takes up exudate.

TIELLE* Hydropolymer Dressing is indicated for the management of chronic and acute, low to moderately exuding, partial and full thickness wounds including:

- Superficial wounds
 1. Minor abrasions
 2. Skin Tears
 3. Second Degree Burns

TIELLE* Hydropolymer Dressing should be used under health care professional direction for the following indications:

- Pressure ulcers
- Lower extremity ulcers
 1. Venous
 2. Arterial
 3. Mixed etiology
- Diabetic ulcers
- Donor sites

TIELLE* Hydropolymer Dressing is suitable for use under compression bandaging.

PRECAUTIONS

TIELLE Dressing is not indicated for use on the following:

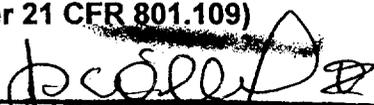
- Third degree burns
- Lesions with active vasculitis as this type of ulcer needs more frequent observation by a healthcare professional.

TIELLE Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ ^{and} Or Over-The-Counter Use ✓
(Per 21 CFR 801.109)



(Division Sign-Off) * Trademark
Division of General Restorative Devices
510(k) Number K983394

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