2/18/99



## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K98-4187

1. **Submitter's Identification:**

Crosstex® International
10 Ranick Road
Hauppauge, NY 11788
Contact: Mr. Richard Allen

Date Summary Prepared:

November 19, 1998

2. **Name of the Device:**

Crosstex Non-Woven Sponges

3. **Predicate Device Information:**

a) Nu Gauze General Use Sponges, Johnson & Johnson, K#8211501
b) The Nova Gauze External Sponge, American Threshold, K#830473
c) Versalon, Kendall, K#812736

4. **Device Description:**

The Crosstex Non-Woven Sponges consist of non-woven materials quarter folded into:

- 2 X 2" (light) 4-Ply
- 2 X 2" (Premium) 4-Ply
- 3 X 3" (Premium) 4-Ply
- 4 X 4" (Premium) 4-Ply

sponges used for the absorption of liquids from the patient's skin.

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5. Intended Use:

Crosstex Non-Woven Sponges are intended, for medical purposes, to be placed directly on a patient's wound or burn to absorb excess body fluids or exudate.

6. Comparison to Predicate Devices:

All of the predicate device non-woven sponges are made from hydroentangled spunlace substrates. The Crosstex Non-woven Sponge is similar to the J&J Nu-Gauze with a 65/35 Rayon/Polyester composition, similar unit weight, similar single ply thickness, similar absorption time and similar absorption capacity.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Biocompatibility testing and physical testing including thickness, tensile strength, elongation, bending length, absorption time and absorption capacity, per ERT and EP standards, met relevent testing requirements.

8. Discussion of Clinical Tests Performed:

Non-Applicable

9. Conclusions:

We have demonstrated that the Crosstex Non-Woven Sponges are substantially equivalent to the predicate devices. We have tested the sponges and they meet applicable voluntary standards. There are no safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Ms. Susan D. Goldstein-Falk
Crosstex® International
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K984187
Trade Name: Crosstex Non-Woven Sponges
Regulatory Class: Unclassified
Product Code: EFQ
Dated: November 19, 1998
Received: November 23, 1998

Dear Ms. Goldstein-Falk:

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 (Act). 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 (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, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) Number (if known): K984187

Device Name: Crosstex Non-Woven Sponges

Indications For Use:

Crosstex Non-Woven Sponges are intended, for medical purposes, to be placed directly on a patient's wound or burn to absorb excess body fluids or exudate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984187