

JAN 20 2000

TECHStyles

K992436

**PREMARKET NOTIFICATION
510(k) SUMMARY**
(As Required by 21 CFR 807.92(c))

June 30, 1999

Contact Person: Stephanie Howard

Device

Trade name – GOWN BACK

Common name – Surgeon's vest or gown back

Classification name – Surgical gown - 21 CFR 878.4040

Legally marketed predicate device

Optima® Surgical Gowns

Orex Surgeon's Vest

White Knight Surgeon's Vest

Description and Conclusions

The device is a vest, commonly called a Gown Back, with a front snap opening. The Gown Back is fluid repellent; it is Single Use. The primary intended use for the Gown Back is as a sterile vest to be worn over a surgeon's gown during procedures or in situations when the surgeon's back needs to be considered sterile. It provides a supplementary layer of protection for the chest and back in light to moderate fluid situations. The Gown Back is not a primary protective garment. The vest design does not provide complete coverage, and the fabric is fluid repellent, not a fluid barrier.

Comparison

Optima® Surgical Gowns and Techstyles, Inc. Gown Back are made of the same nonwoven fabric, the same color and have been treated with the same fluid repellency treatment. The Orex Surgeon's Vest and the White Knight Surgeon's Vest are functionally the same as Techstyles, Inc. Gown Back, though they are of different fabrics.



JAN 20 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Stephanie T. Howard
Techstyles, Incorporated
16415 Addison Road, Suite 850
Addison, Texas 75001

Re: K992436
Trade Name: Gown Back, Model 13-403N; 13-404N; 13-405N
Regulatory Class: II
Product Code: FYA
Dated: December 1, 1999
Received: December 6, 1999

Dear Ms. Howard:

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 (Pre-market 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 Good Manufacturing Practice 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

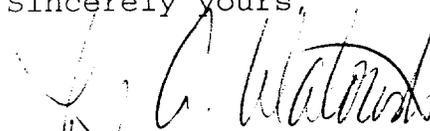
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 – 4/24/96

Applicant: Techstyles, Inc.

510(k) Number (if known): K992436

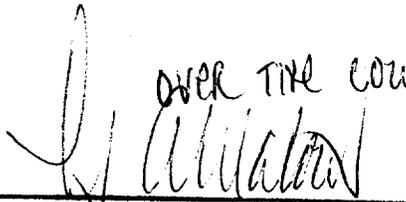
Device Name: GOWN BACK, Surgeon's Vest – Single Use/Disposable

Indications For Use:

Target population: *Surgeons or other members of the surgical team.*

The Gown Back is to be worn over a surgeon's gown during procedures and in situation when the surgeon's back needs to be considered sterile. This accessory device is used to protect both operating room personnel and the surgical patient from the transfer of microorganisms, body fluids, and particulate matter.

Concurrence of CDHR, Office of Device Evaluation (ODE)

OVER THE COUNTER DEVICE


(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 992436