AUG 1 9 2002

Attachment A

9.0 510(k) Summary K013958

INDUS TEXTILES O.R. TOWELS

Manufacturer:	Indus Textiles, Inc. PMB # 148 7723 Tylersville Place Blvd. Westchester, Ohio 45069
Regulatory Affairs Contact:	Michele Vovolka P.O. Box 848 Grayslake, Illinois 60030
Telephone:	(847) 856-0355
Date Summary Prepared:	November 20, 2001
Product Trade Name:	Indus Textiles O.R. Towels
Common Name:	Surgical Towel
Classification:	Class II per 21 CFR §878.4370
Predicate Devices:	Broadline O.R. Towels A Plus International O.R. Towel Com-Med O.R. Towel

Description: The Indus Textiles O.R. Towels are made of 100% cotton that have been pre-washed and delinted. The towels are offered sterile and non-sterile and are available in blue.

Intended Use: This is a single use disposable surgical towel intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The O.R. Towel is further used as a fluid-absorbing towel during surgery or as a device to dry hands of the O.R. personnel.

Attachment A

510(k) Summary (Continued)

Substantial Equivalence:

The Indus Textiles O.R. Towels are substantially equivalent to the Broadline O.R. Towels, A Plus O.R. Towels, and Com-Med TO.R. Towels in that they provide the following characteristics:

- Intended use is the same
- Size, configuration, color are similar
- Made of 100% cotton
- Physical properties are similar

Summary of Testing:

The following tests were performed on the finished Indus Textiles O.R. Towels:

Test Method	**Standard Used**
Absorptive Capacity	IST 10.1 and ASTM D1117
Imbibition Test	AATCC 8-1996 – Saline Crocking
Flammability	16 CFR 1610.4
Tearing Resistance	ASTM D1424-96
Grab Tensile	ASTM D1682

The material and blue dye are identical to the predicate devices listed above. The toxicology and biocompatibility have been thoroughly investigated and documented with these predicate devices. Biocompatibility testing was initiated for the towel post gamma and EtO sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2002

Indus Textiles, Incorporated
Ms. Michele H. Vovolka
Vantage Consulting International, Limited
P.O. Box 848
Grayslake, Illinois 60030

Re: K013958
Trade/Device Name: IndusTextiles O.R. Towel (Blue, Sterile and Non-Sterile)
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: June 28, 2002
Received: July 1, 2002

Dear Ms. Vovolka:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

510(k) Number (if known): K013958

Device Name: Indus Textiles O.R. Towel (Blue, Sterile / Non-Sterile)

Indications For Use:

This is a single use disposable surgical towel intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The O.R. towel is also to be used for the absorption of fluids, including blood and body fluids or as a general use towel for drying hands.

(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)

Qian S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K013958