

JUL 30 2007

**SECTION 5 - SUMMARY OF SAFETY AND EFFECTIVENESS**

**510(k) Summary** This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

This summary is applicable to Nonsterile Surgical Drapes and Surgical Drape and Surgical Accessories.

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**Submission**

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**Submission**

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**Date Prepared:**

October 3, 2006

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Vortek Surgical, Inc.  
Traditional 510(k) Premarket Submission  
Endodrape™ Surgical Drapes

**Name of device:** Endodrape™

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**Classification Name:** Drape, Surgical

**Device Classification:** 2

**Product Code:** KKK

**Predicate Device 510(k):** K050508, K020581

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### **Predicate Device**

There are several predicated devices currently on the market that have similar function and are made from the same or similar materials. Vortek Surgical, Inc. considers the surgical drapes manufactured by HVO, Inc and Medical Concepts Development to be substantially equivalent in composition, function and intended use to its Endodrape™ surgical and diagnostic procedure drapes.

### **Device Description**

The Endodrape™ surgical and diagnostic procedure drapes manufacture by Vortek Surgical, Inc. are non-sterile, single use, disposable barriers intended to be used by medical professionals as a protective patient covering; to protect clinical staff and equipment from patient secretions; and help maintain a cleaner procedural site. The drapes are blue in color and are a non-woven fabric that will be manufactured under private label to Vortek Surgical. The Endodrape™ fabric itself is a repellent treated, non-woven fabric manufactured under the trade name of Sontara by the contract manufacturer to Vortek Surgical, Inc. There are no reinforced areas of the drape. The drape is 0.13 inch thick and measures 43" x 49" and is without any areas of reinforcement. The fibers used in the drape are mechanically bonded together.

Surgical and diagnostic drapes have been manufactured and marketed for a number of years that are made from the same or similar materials and have been used successfully under the same or similar conditions. The Endodrape™ surgical and diagnostic procedure drapes are blue in color; non-woven, non-sterile, single uses drapes.

### **Indications for Use**

The intended use of the Endodrape™ surgical and diagnostic procedure drape manufactured by Vortek Surgical is for patients receiving and/or medical professionals performing a non-sterile diagnostic procedure for colonoscopies to

help protect the patient and staff from bodily secretions and to maintain a cleaner procedural site. The device is a single use disposable drape that is provided non-sterile. The device can, however, be EtO (ethylene oxide) sterilized by the end user prior to use.

### **Clinical Performance**

Clinical performance for non-sterile, disposable surgical drapes is not applicable for this product. Numerous predicated devices (surgical drapes) exist and have been used extensively for a number of years that are made from the same or similar materials.

### **Non-Clinical Performance (Bench Testing)**

Non-clinical performance (bench) testing of the Endodrape™ surgical and diagnostic procedure drapes consisted of Physical, Mechanical, Liquid Barrier Penetration and Biocompatibility, in accordance with applicable industry recognized test methods. The Endodrape™ surgical and diagnostic procedure drapes were found to be acceptable for its intended use.

Product characteristics for the Endodrape™ drapes and the predicate surgical drapes manufactured by HVO and Medical Concepts Development are shown in the following Substantial Equivalence Comparison Table. The fabric properties for Endodrape™ surgical and diagnostic and are believed to be identical to those properties found in HVO's and Medical Concepts Development's surgical drapes.

All physical and mechanical testing was performed in accordance with the applicable standards and regulations set forth by ASTM (American Society for Testing and Materials), INDA (Association of the Non-woven Fabrics Industry), the US Code of Federal Regulations (CFR), the American Association of Textile Chemist and Colorists (AATCC) and the International Organization for Standardization (ISO), and follow the recommendations established in the FDA Guidance Document for Surgical Gowns and Surgical Drapes, August 1993.

The materials used to manufacture Endodrape™ surgical and diagnostic procedure drapes are well-known and commonly used materials to manufacture other surgical drapes and have been in use for many years. Refer to Section 18 of this premarket notification submission for further information.

**Substantial Equivalence Comparison  
 Vortek Surgical, Inc. vs. HVO, Inc. and Medical Concepts Development**

<b>PRODUCT CHARACTERISTIC</b>	<b>PROPOSED DEVICE</b>	<b>PREDICATE DEVICE</b>	<b>PREDICATE DEVICE</b>
510(k) Number	TBD	K050508	K020581
Manufacturer	Vortek Surgical, Inc.	HVO, Inc.	Medical Concepts Development
Product Name	Endodrape™	Various	ColoShield Colonoscopy Drape Model E2000
Indications for Use	<p>The intended use of the Endodrape™ surgical and diagnostic procedure drape manufactured by Vortek Surgical is for patients receiving and/or medical professionals performing a non-sterile diagnostic procedure for colonoscopies to help protect the patient and staff from bodily secretions and to maintain a cleaner procedural site. The device is available as Prescription Use. The device is a single use disposable drape that is provided non-sterile. The device can, however, be EtO sterilized by the end user prior to use.</p>	<p>The intended use of the non-sterile surgical drapes manufactured by HVO is as a protective patient covering, such as to isolate surgical incisions from microbial and other contamination. These proposed devices are intended to undergo sterilization by the customer prior to use in the sterile setting.</p>	<p>The intended use of the surgical drapes manufactured by Medical Concepts Development is during colonoscopy procedures to protect the clinical staff from patient secretions and to help maintain a cleaner procedural site.</p>
Contraindications	NA	NA	NA

Vortek Surgical, Inc.  
 Traditional 510(k) Premarket Submission  
 Endodrape™ Surgical Drapes

Environment Where Used	Surgical and diagnostic centers	Surgical and diagnostic centers	Surgical and diagnostic centers
Number of Uses	single	single	single
Provided and Used Non-Sterile	Yes/Yes	Yes/No (ETO)	Yes/No (ETO)
Sizes	43" x 49" (only)	various	various
Thickness	0.13 inch	Same or similar	Same or similar
Material Description	Non-woven fabric; various man-made and synthetic fibers:  (e.g., Sontara, Krayton Velcro, cellulose, polyester, LDPE, medical grade tapes, SMS, adhesives and polyfoam, etc.).  Color: blue.	Same or similar materials	Same or similar materials
Material Characteristics:	for Sontara		Same or similar
• Weight	1.9 oz/yd	Same or similar	Same or similar
• Grab Tensile Strength	22lb/in	Same or similar	Same or similar
• Water Impact	1.5 g	Same or similar	Same or similar
• Water Hydrostatic	22 cm	Same or similar	Same or similar
• Surface Wetting Spray	90 (range: 0-100)	Same or similar	Same or similar
• Alcohol Repellency	9 (range: 0-10)	Same or similar	Same or similar
• Flame Retardency	DNI – Class I	Same or similar	Same or similar

Biocompatibility:			
• Cytotoxicity	Non cytotoxic	Same or similar	Same or similar
• Skin Irritation	Non skin irritant	Same or similar	Same or similar
• Skin Sensitivity	Non skin sensitizing agent	Same or similar	Same or similar
AAMI Liquid Barrier Classification	Level 1 ≤ 4.5 g	Same or similar	Same or similar

**Packaging and Sterilization**

The Endodrape™ surgical and diagnostic procedure drapes will be manufactured under private label to Vortek Surgical, Inc. The drapes are supplied non-sterile to the customer. Each drape is precut and measures 43” x 49” in size. This is only size drape for this submission. Each surgical drape is individually packaged in a heat sealed poly bag and will be shipped to the customer in quantities of 20 per box.

The Endodrape™ surgical and diagnostic procedure drapes are single use disposable drapes that are provided non-sterile and **ARE NOT INTENDED TO BE STERILIZED BY THE END USER**. The device can, however, be EtO (ethylene oxide) sterilized by the end user if they choose to sterilize it prior to use using the instructions provided by Vortek Surgical in the package insert.

**Biocompatibility**

The Endodrape™ surgical and diagnostic procedure drapes are intended to be used such that they have **limited** skin contact with the patient, less than 24 hours, as defined in ISO 10993-1:2003. The materials used to manufacture the Endodrape™ are well-known and commonly used for other surgical drapes and the predicate devices. As such, only Cytotoxicity, Sensitization and Irritation testing are required to be performed on the material. Testing of the material was performed by the contract manufacturer to Vortek Surgical, Inc. and was done in accordance with ISO 10993-1:2003. Refer to Section 15 of this premarket notification submission for further information. The Endodrape™ surgical and diagnostic procedure drapes were found to be non-cytotoxic, non-irritating and non-skin sensitizing.

The biocompatibility testing that was performed on the surgical and diagnostic procedure drapes manufactured for Vortek Surgical, Inc. (by its contract

manufacturer) was done so on product that had been subjected to EtO sterilization, as some of the medical device companies that also purchase these surgical and diagnostic procedure drapes (from the same contract manufacturer) may or may not indicate that the product is to be sterilized prior to use.

Therefore, biocompatibility testing that was performed on these surgical and diagnostic procedure drapes manufactured for Vortek Surgical, Inc. (by its contract manufacturer) represent worst case conditions compared to identical product that has not been EtO sterilized, as there is the possibility of residual EtO by-products being left in the material. See attached biocompatibility statement memo from the contract manufacturer.

### **Conclusion**

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics. But, it can be demonstrated that the device is as safe and effective as the predicate device and the new device do not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the Endodrape™ surgical and diagnostic procedure drapes and the predicate device cited do not raise any different questions regarding its safety and effectiveness.

The Endodrape™ surgical and diagnostic procedure drapes, as designed, is as safe and effective as the predicate device and the device and therefore is determined to be substantially equivalent to the referenced predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 30 2007

Vortek Surgical, LLC  
C/O Mr. Jay Y. Kogoma  
Third Party Reviewer  
Intertek Testing Services NA, Incorporated  
2307 East Aurora Road, Unit B7  
Twinsburg, Ohio 44087

Re: K070406

Trade/Device Name: Endodrape™ Surgical and Diagnostic Procedure Drape  
Regulation Number: 21 CFR 878.4370  
Regulation Name: Surgical Drape and Drape Accessories  
Regulatory Class: II  
Product Code: KKK  
Dated: July 17, 2007  
Received: July 18, 2007

Dear Mr. Kogoma:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070406

Device Name: Endodrape™ surgical and diagnostic procedure drape.

Indications for Use: The intended use of the Endodrape™ surgical and diagnostic procedure drape manufactured by Vortek Surgical is for patients receiving and/or medical professionals performing a non-sterile diagnostic procedure for colonoscopies to help protect the patient and staff from bodily secretions and to maintain a cleaner procedural site. The device is a single use disposable drape that is provided non-sterile. The device can, however, be EtO (ethelene oxide) sterilized by the end user prior to use.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

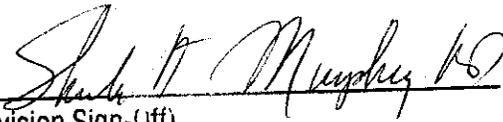
AND/OR

Over-The-Counter Use X \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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