DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 14, 2014

Whitney Medical Solutions
C/O Mr. Mark Job
Regulatory Technology Services LLC
1349 25th Street NW
Buffalo, MN 55313

Re: K141438
Trade/Device Name: Whitney Medical Solutions eShield
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape
Regulatory Class: Class II
Product Code: KKX
Dated: July 16, 2014
Received: July 22, 2014

Dear Mr. Job,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indications for Use Statement is provided on the following page.

Indications for Use Statement

510(k) Number (if known): K141438

Device Name: Whitney Medical Solutions eShield

Indications for Use:

Whitney Medical Solutions equipment drapes are to be used to cover a variety of surgical and non-surgical equipment in various settings throughout the clinical setting. These drapes are used to protect the equipment from contamination during various procedures.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary for the Whitney Medical Solutions eShield

The 510(k) Summary is provided on the following pages.

510(k) Summary
Whitney Medical Solutions eShield

510(k) Summary	This 510(k) summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	Whitney Medical Solutions
Submitter	Whitney Medical Solutions 6153C West Mulford Street Niles, IL 60714 Tel: 847-966-6161 Fax: 847-966-6168
Contact Person	Saagar Patel
Date Prepared	August 7, 2014
Device/ Trade Name	Whitney Medical Solutions eShield
Device Common Name	Surgical Drape
Regulation Name	Surgical Drape and Drape Accessories
Regulation Number	21 CFR 878.4370
Regulatory Class	Class II
Product Code	KKX
Classification Panel	General and Plastic Surgery
Predicate Devices	K050322
Intended use	Whitney Medical Solutions equipment drapes are to be used to cover a variety of surgical and non-surgical equipment in various settings throughout the clinical setting. These drapes are used to protect the equipment from contamination during various procedures.

Device Description

The Whitney Medical Solutions' eShield consists of polyethylene film (and an adhesive pad in some models) with tear guide tape and a zipper that allows the cover to be torn fairly straight across it. There is also a double sided tape below the zipper that is used as a redundant closure method with the cover being folded twice and sealed against it. The device is provided to the user sterile, is labeled for single use only and not intended for resterilization or reprocessing. The sterile eShield is sterilized using a validated irradiation sterilization method.

eShield Model Configurations

Part Name	Part Number	W (in)	H (in)	Adhesive ring
Cell Phone Size	EC2100	9	14	No
Digital Camera Size	EC2200	9	14	Yes
Tablet Size	EC2300	14	18	No
SLR Camera Size	EC2400	14	22	Yes
Cell Phone Size with Zipper	EC2500	9	14	No
Digital Camera Size with Zipper	EC2600	9	14	Yes
Tablet Size with Zipper	EC2700	14	18	No
SLR Camera Size with Zipper	EC2800	14	21	Yes

Performance data

Whitney Medical Solutions' eShield was tested to and meets the performance specifications for the tests listed below. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Standard	Acceptance Criteria
ISO 10993-1 Biological evaluation of medical devices – Part 1: general requirements	Under the conditions of the study, the device is not a sensitizer, an irritant, is non-toxic and Non-cytotoxic.
ASTM F1886 Standard test method for determining integrity of seals for flexible packaging(sterility)	Product meets inspection requirements of standard for visual defects found.
AAMI/ANSI/ISO 11607-1 Packaging for terminally sterilized medical devices – part 1	Used as guideline for sterilization process. Adhered to specified requirements and test methods. Device sterilization dose will maintain a SAL 10^{-6}
ASTM F88/F88M Standard test method for seal strength of flexible barrier materials	Meets or exceeds minimum internal acceptance criteria of 1 PLI after ASTM F1980 and ASTM D4169.
ASTM F 2096 Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)	Meets performance criteria set by standard for maintaining pressure for 5 seconds under 1" of water after ASTM F1980 and ASTM D4169
AAMI/ANSI/ISO 11137-2 Sterilization of healthcare products – radiation – part 2 establishing the sterilization dose	Used as guideline for sterilization process. Adhered to specified requirements and test methods. Device sterilization dose will maintain a SAL 10^{-6}
AAMI/ANSI/ISO 11737-1,2 Sterilization of medical devices-microbial methods part 1:	Used as guideline for sterilization process. Adhered to specified requirements and test methods. Device sterilization dose will maintain a SAL 10^{-6}

determination of the population of microorganisms on product; part 2: tests of sterility performed in the definition, validation and maintenance of a sterile process	
ASTM F1671/F1671M Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system.	Under the conditions of the study, the device does not allow viral penetration nor plaque formation.
ANSI/AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	The device meets the acceptance criteria set by the standard (AQL 4% and RQL of 20%) and up to one plaque growth per 13 samples.
ASTM D882 Standard test methods for tensile properties of thin plastic sheeting. (Ophthalmic)	The device meets the tensile acceptance criteria set by the standard for equivalence when the films are within 400 psi of each other.
ASTM D1004 Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting	The device meets the tear acceptance criteria set by the standard for equivalence when the films are within 89.53 grams in machine direction and 42.6 grams in transverse direction
ASTM D3420 Standard Test Method for Pendulum Impact Resistance of Plastic Film1	The device meets the puncture acceptance criteria set by the standard for equivalence when the films within 9.4% .
16 CFR Part 1610 Standard for the Flammability of Clothing Textiles	The device meets the flammability acceptance criteria set by the standard for a Class 1 rating with a burn time of ≥3.5 seconds.

Summary of Substantial Equivalence

The Whitney Medical Solutions eShield utilizes substantially equivalent performance attributes and safety components as the predicate device. It shares the following similarities to the predicate device:

- They have the same intended use
- They have the same or similar physical and mechanical specifications
- The materials of construction are the same
- They have the same principle of operation and performance
- They both meet applicable performance requirements
- They are both biocompatible

Design Feature	Whitney Medical Solutions' eShield (K14XXXX)	MICROTEK MEDICAL, INC. (K050322)	Substantial Equivalence
Indications for Use	Whitney Medical Solutions equipment drapes are to be used to cover a variety of surgical and non-surgical equipment in various settings throughout the clinical setting. These drapes are used to protect the equipment from contamination during various procedures.	Microtek Medical equipment drapes are to be used to cover a variety of surgical and non-surgical equipment in various settings throughout the clinical setting. These drapes are used to protect the equipment from contamination during various procedures.	**SAME**. The proposed device and the predicate devices have the identical claim of protecting equipment in the clinical setting from contamination during various procedures.
Principle of Operation	The proposed device is used to provide a contamination barrier between a variety of surgical and non-surgical equipment in various clinical settings.	The predicate device is used to provide a contamination barrier between a variety of surgical and non-surgical equipment in various clinical settings.	**SAME**.
Single Use	Yes	Yes	**SAME**.
Material	Polyethylene	Polyethylene	**SAME**.
Disposable Adhesive Ring	Yes	No	Differences do not raise new questions of safety and effectiveness.
Viral Penetration ASTM F1671	Pass	Unknown	**SAME.**
Tensile Test ASTM D882	Pass	Unknown	Differences do not raise new questions of safety and effectiveness.
Tear ASTM D1004	Pass	Unknown	Differences do not raise new questions of safety and effectiveness.
Puncture Test ASTM D3420	Pass	Unknown	**SAME.**
Flammability 16 CFR Part 1610	Class 1	Class 1	**SAME.**
Physical Specifications – all models	Width: range 9 – 14 inches Height: range 14 – 22 inches	Width: 15 inches Height: 13 inches 4 models: 20" circular	**SAME.** Differences do not raise new questions of safety and effectiveness.
Packaging - pouch	Single barrier Tyvek/-LDPE film	LDPE Film with Tyvek	**SAME.** Differences do not raise new questions of safety and effectiveness.
Sterilization	Gamma	ETO/some models provided non-sterile	**SAME.** Both sterilization methods assure

			10^{-6} SAL. Differences do not raise new questions of safety and effectiveness.
Labeling	Sterile, Single Use, Disposable	Sterile/Non-sterile, Single Use, Disposable	**SAME.** Differences do not raise new questions of safety and effectiveness.
Instruction for Use	Provided	Not provided, these drapes have generally known usages and instructions.	**SAME.** Differences do not raise new questions of safety and effectiveness.
Biocompatible	Under the conditions of the study, not an irritant. Under conditions of the study, not a sensitizer. Under conditions of the study, non-cytotoxic. Under conditions of the study, non-toxic.	Unknown	**SAME.**

Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the device is as safe as effective as the predicate device. Whitney Medical Solutions believes the Whitney Medical Solutions eShield is substantially equivalent to the Microtek Medical, Inc. (K050322).