K121382

4.0 510(k) Summary

In accordance with 21 CFR sections 807.92, Westmed, Inc. is submitting the following 510(k) summary:

DEC 6 2012

4.1 Date of Preparation

May 1st, 2012

4.2 Submitter Information:

Westmed, Inc.
Company Representative: R. Jon McKinnon, President
5580 S. Nogales Highway
Tucson, AZ 85706
United States
USA
FDA Registration No.: 2028807
Owner / Operator No.: 9006543

4.2 Preparer of Submission and Contact for Information:

Westmed, Inc
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United States
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R. Jon McKinnon (contact for correspondence and information)
Telephone: (800) 724-2328 / Fax (520) 294-2780

4.3 Name of Device:

Proprietary Name:	BlockAide™ Filter.
Common Name:	Disposable bacterial/viral filter.
Classification Name:	Breathing circuit bacterial filter, [21 CFR 868.5260(a)].
Regulation Number:	21 CFR 868.5260(a) for Breathing circuit bacterial filters.
Product Code:	73 CAH
Class:	Class II (performance standards)

4.4 Substantial Equivalence:

This submission establishes the substantial equivalence of the Westmed, Inc. BlockAide™ Filter to five predicate devices:

(1)	The All Flow Pulmonary Filter,	K043148, SE letter: 12/13/04.
(2)	The SpiroSafe Disposable PF Filter,	K973314, SE letter: 11/21/97.
(3)	The KOKO Disposable PF Filter II,	K934475, SE letter: 10/21/93.
(4)	The MicroGard Disposable PF Filter,	K934272, SE letter: 11/24/93.
(5)	The MultiSPIRO Disposable PF Filter,	K951410, SE letter: 04/24/95.

4.5 Description of the Device:

The BlockAide™ Filter, manufactured by Westmed, Inc., is a disposable, single-use barrier type, bi-directional filter fabricated from a plastic resin that is supplied to the customer packaged and non-sterile. Fabricated with a filtering medium that is highly effective in reducing the numbers of both bacterial and viral contaminates that may be present in a patient's exhaled gas, the device's design also minimizes the resistance to air flow. The product is intended to protect both the patient and pulmonary function instruments from potential transmission of pathogens by droplets and aerosols.

The device consists of two molded plastic housings enclosing a disk of filter media. To avoid confusion, the patient housing side is made from an opaque plastic and the machine housings are fabricated from the same plastic but with different number molded into the housing to identify machine end. The numbered end fits the machine and the opaque end is for the patient side; therefore making clear definition as to which end is used for the patient and the machine.

Figure 1 **Example of Filter Part No. 6901-E with patient and machine housing components separated:**

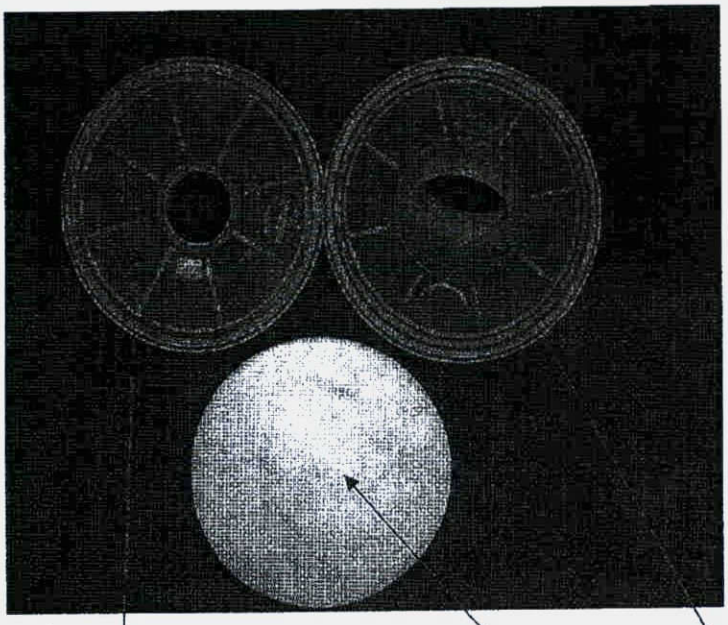
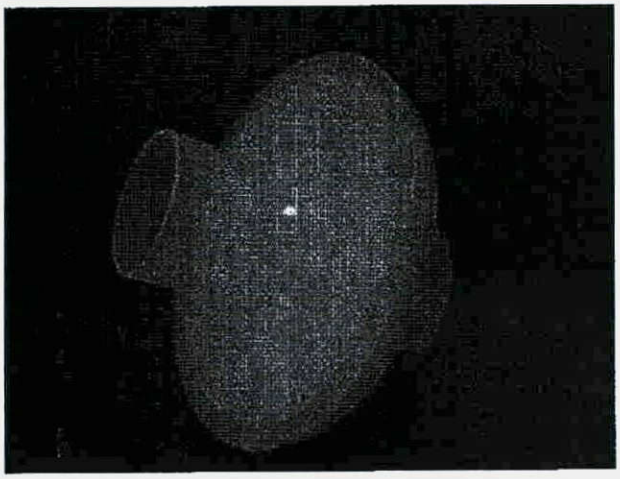


Figure 2, Example of filter assembled:



Because spirometers can have different sensor diameters, the BlockAide™ Filter is available in six different sizes with a number that correlates with their respective part numbers. The following chart lists the size and number of each model:

Filter Chart

BlockAide™ Filter Part No.	number combination (patient housing / machine housing)	I.D / O.D (mm)
6901-R/E	Opaque / Opaque 1	27.23 / 30.18
6902-R/E	Opaque / Opaque 2	34.48 / 33.15
6903-R/E	Opaque / Opaque 3	45.47 / 47.45
6904-R/E	Opaque / Opaque 4	26.26 / 28.73
6905-R/E	Opaque / Opaque 5	29.52 / 32.77
6906-R/E	Opaque / Opaque6	37.39 / 33.63

4.6 Intended Use of the Device:

The BlockAide™ Filter is designed as a disposable and single-use bi-directional filter for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary function testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic purposes.

4.7 Technological Characteristics in Comparison to the Predicates:

The BlockAide™ Filter has no differences in Technological characteristics and is substantially equivalent to the five predicate devices with respect to the following design characteristics and functions:

1. The devices are intended for use in reducing the possible cross contamination of spirometers and pulmonary function testing instruments from bacterial and/or viral pathogens by droplets, particulates, and/or aerosols.

2. The devices function as a barrier type, bi-directional filter, which is within a sealed double port assembly, with one port contacting the patient's mouth and the other port to be attached to the spirometers or pulmonary function-testing instrument.

3. The device housing components are fabricated from the same or similar plastic resin materials used in the predicate devices. The filter media is the same as or similar to that used in the predicate devices. These materials have long and extensive use in medical device applications.

4. The devices have been demonstrated to function effectively in reducing high challenge numbers of bacterial and viral contaminates.

5. The devices provide air filtration while minimizing airflow resistance through the filter assemblies to the pulmonary test equipment.

6. The BlockAide™ Filter met the recommendations of the American Thoracic Society's Standardization of Spirometry (1994 update) for minimal recommendations for Diagnostic Spirometry Equipment with in-line filters; i.e., that the measuring equipment as attached to the filter have air flow resistance of less than 1.5 cm H_2O/L/s.

4.8 Conclusions drawn from the Non-Clinical Tests:

Data provided in this submission indicate that the basic functional characteristics of the BlockAide™ Filter are substantially equivalent to those of the predicate devices.

1. Bacterial Filtration Efficiency (BFE) testing demonstrated the BlockAide™ Filter, at an increased challenge, to be %BFE = > 99.9%.

   Viral Filtration Efficiency (VFE) testing demonstrated the BlockAide™ filter, at an increased challenge, to be %VFE = > 99.9%.

2. Airflow resistance testing demonstrated the device to an average of 5.028 cm H_2O/SLPM at 720 L. (Ref. 760 mm HGA 70 °F), which is approximately 0.419 cm H_2O/L/sec.

3. Filter dead space was demonstrated to be approximately 54 mL.

4. The BlockAide™ Filter meets the recommendations of the American Thoracic Society's Standardization of Spirtometry (1994 update) for minimal recommendations for Diagnostic Spirometry Equipment with in-line filters i.e., that the measuring equipment as attached to the filter have air flow resistance of less than 1.5cm H_2O/L/s.

5. The device was categorized as a surface device with skin and mucosal membrane and as an external communicating device with tissue contact both for limited <24 hours contact. As such per FDA Memorandum G-95 Table 1 the following tests were conducted per ISO 10993-1 cytotoxicity, sensitization and intracutaneous reactivity. This testing showed the device to be bio-compatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 6, 2012

Mr. R. Jon McKinnon
President
Westmed, Incorporated
5580 South Nogales Highway
TUCSON AZ 85706

Re: K121382
Trade/Device Name: BlockAide™ Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: November 14, 2012
Received: November 23, 2012

Dear Mr. McKinnon:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121382

Device Name: BlockAide™ Filter

Indications for Use:

The Westmed, Inc. BlockAide™ Filter is designed as a disposable and single-use, bi-directional filter for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary function testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic applications.

Prescription Use __X__ OR Over-the-Counter Use_____
(part 21 CFR 801. Subpart D) (part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121382