K131402

MAR - 3 2014

510(k) Summary
For
VISICLEAR SMOKE EVACUATION SYSTEM

Buffalo Filter LLC
5900 Genesee Street
Lancaster NY 14086
Phone (716) 835 7000
Fax No (716) 835 3414

Contact Carrie Fermin
Director of Quality and Regulatory Affairs
Phone (716) 835-7000
Fax No (716) 835 3414

Summary Date October 21, 2013

1. **Device Name**

Trade Name:	VISICLEAR Smoke Evacuation System
Common Name:	Smoke Evacuator
Classification Name:	Air Handling Device for a surgical operating room (21 CFR 878.5070, Product Code FYD). Class II

2. **Predicate Device**

Buffalo Filter, LLC ("Buffalo Filter") claims substantial equivalence to:

a. Conmed Corporation. Conmed Aer Defense Smoke Evacuator (K091139)

b. Buffalo Filter. Porta PlumeSafe 601 Smoke Evacuation System (K924732)

3. **Description of Device**

The VISICLEAR smoke evacuation system is a self-contained system that is used to remove and filter surgical smoke. The device is intended for general electrosurgical and laser applications for removing smoke generated by electrosurgery and laser procedures.

The device is constructed using the same materials and design specifications commonly found in the predicate devices in the smoke evacuation marketplace. The smoke evacuator is comprised of a vacuum motor, aluminum, and plastic components combined with sound reducing insulation. The vacuum motor is used to draw the smoke from the surgical site, through the vacuum tubing and into the VISICLEAR filter where the surgical smoke is processed by a series of filtration stages.

The vacuum flow rate for the VISICLEAR smoke evacuation device ranges from a minimum of 5 liters per minute (LPM) in Laparoscopic Mode to 30 cubic feet per minute in Open Mode. These flow rates are substantially equivalent to the flow range for the predicate devices.

The filter for the VISICLEAR smoke evacuation system, like the filters for the predicate devices, is a replaceable self-contained filter that is completely enclosed to protect health care personnel from potential contamination during filter changes. The VIROSAFE 135 filter ("VS135") is an Ultra Low Penetration Air (ULPA) grade with carbon filter that has filter efficiency of 99.999% for particle sizes of 0.1 to 0.2 microns or greater. These characteristics are consistent with the predicate devices.

The filter life of the VS135 is based on flow rate through the filter and is 35 hours in Laparoscopic Mode, and 18 hours at Open Mode. The filter life for the predicate devices is based on a time of use of 35 hours on Lap Mode and 18 hours on Open Mode. Bench testing has shown the filter life is substantially equivalent to the predicate filters.

The life of the filter is based on the initial time decrementing during operation, specifically when the smoke evacuator motor is operating. The smoke evacuator software is programmed to decrement the filter at the appropriate rate dependent on the selected mode. The filter life is an initial integer stored on an RFID tag during filter assembly that is programmed with the maximum filter life time. During operation, the smoke evacuator decrements that filter time from the RFID tag until the time expires. Since the filter life is stored directly on the RFID tag located on each filter, when the filter is moved from one smoke evacuator to another, remaining filter life is recognized by any smoke evacuator. Once the filter is expired, time has decremented to zero, the filter will no longer operate in any smoke evacuation system. This operation cannot be bypassed, as time cannot be added back to the filter by the end user. The software verification confirmed the effectiveness of this feature to limit the filter use to only the intended life. The testing per IEC 60601-1-2 and IEC 60601-1-1 confirmed the safety and effectiveness of the technology for use in the smoke evacuation system.

4. Intended Use

The VISICLEAR Smoke Evacuation System is designed to remove and filter smoke, aerosols produced during electrosurgical and laser procedures.

Indications for use for the VISICLEAR smoke evacuation system include:

a. To remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures

5. Description of Safety and Substantial Equivalence

Substantial equivalence is based on two (2) predicate devices. All the above referenced predicates are Air-Handling Apparatus for a surgical operating room defined in 21 CFR 878.5070.

The Buffalo Filter VISICLEAR smoke evacuation system was verified and validated through bench testing designed and conducted to show that the device operates as safe and as effective as the predicate devices, K091139 and K924732.

Like the predicate devices, the VISICLEAR is used in hospitals, operating room theaters, and doctor's offices and requires physician's prescription for use. The device and all predicates are not intended for patient contact.

The VISICLEAR is equivalent in technological characteristics to the predicate devices in that like VISICLEAR, all predicate devices use a vacuum motor, user interface with motor control features, sound reducing insulation, a filter with a specific life expectancy, and accessories such as tubing to capture the surgical smoke. The device utilizes the same materials found in predicate device, 'Aer Defense' with the housing comprised of a combination of plastic and metal, and sound reducing insulation. The VISICLEAR filter is equivalent in design characteristics to the predicate devices, in that multiple layers of filtration are utilized to achieve designed efficiency. These layers include a pre-filter to trap and remove gross particulate; an ULPA grade filter media that captures particulates from 0.1 to 0.2 microns at an efficiency of 99.999%; another layer comprised of virgin activated carbon; and a final filter layer intended to reduce the migration of granular activated carbon from the self-contained filter.

Verification for the VISICLEAR smoke evacuation system included mechanical, electrical, and software testing.

The electrical verification testing showed that the device met its operational mode and electrical design requirements as specified in the test protocol. Electrical safety testing was conducted for the VISICLEAR smoke evacuation system according to IEC/ANSI/AAMI 60601-1 and IEC/ANSI/AAMI 60601-1-2. This testing indicated that the VISICLEAR met all electrical safety requirements for the referenced standards.

The mechanical/performance verification testing showed that the device met its mechanical/performance design requirements as specified in the test protocol. Filter life verification testing was conducted for the VISICLEAR smoke evacuation system to confirm the ULPA efficiency of the filter for the maximum flow rate and filter life time. This testing indicated the filter successfully passed ULPA efficiency after 18 hours of saturation of particles at 30CFM flow rate. Flow Verification testing was conducted for the VISICLEAR smoke evacuation system to verify flow performance outlined in the design specification. This testing indicated that the VISICLEAR met all the specified flow requirements at each of the data points for each of the modes of operation. Laparoscopic Smoke Evacuation Verification was conducted for the VISICLEAR smoke evacuation system to confirm effectiveness at clearing smoke while not reducing the pneumoperitoneum. Smoke removal effectiveness verification testing was completed to demonstrate and quantify the ability of the VISICLEAR to remove smoke aerosols resulting from electrosurgical and laser procedures. Reliability testing was conducted for the VISICLEAR smoke evacuation system to demonstrate the use life of the device and no degradation in performance over that time span. Efficiency testing was conducted to ensure the fourth stage of filtration is adequately capturing the carbon fines.

The software verification testing showed that the device met the operational mode and software design requirements as specified in the protocol.

All test results for the non-clinical bench testing indicate that the VISICLEAR smoke evacuation system is substantially equivalent to the predicate devices, K091139 and K924732.

Validation testing has shown that the VISICLEAR smoke evacuation system has met its operation mode and validation requirements. Test results indicate that the VISICLEAR is substantially equivalent to the predicate devices, K091139 and K924732.

The VISICLEAR smoke evacuation system and the predicate devices do not contact the patient and are substantially equivalent regarding biocompatibility.

Technical Characteristics to Support Substantial Equivalence:

Parameters			
Models	**PPS 601**	**Aer Defense**	**VISICLEAR**
Intended Use	Smoke Evacuation and Filtration	Smoke Evacuation and Filtration	Smoke Evacuation and Filtration
Indications for Use	Evacuation of smoke plume and odor generated during laser or electrosurgery procedures	To remove smoke, aerosols and mitigate odors produced by surgical smoke during electrosurgical procedures	To remove smoke and aerosols from a surgical site; to mitigate odors produced by surgical smoke during electrosurgical and laser procedures.
Target Population	For physicians and trained hospital staff during the use of lasers or electrosurgery	For physicians and trained hospital staff during the use of lasers or electrosurgery	For physicians and trained hospital staff during the use of lasers or electrosurgery
User Interface	Touch Keypad with LED Indicator Lights	Touch Keypad with LED Indicator Lights	Touch Keypad with LED Indicator Lights
Energy Used	Electrical Current	Electrical Current	Electrical Current
Operational Settings	On/Off Switch, Suction level buttons for Motor Control	On/Off Switch, Suction level buttons for Motor Control	On/Off Switch, Suction level buttons for Motor Control
Compatibility with Environment & Other Devices	Compatible, neutral to other devices	Compatible, neutral to other devices	Compatible, neutral to other devices

Intended Marketed Accessories	Tubing, Hoses, & Adaptors – Sterile and Non-Sterile	Electrosurgical pencils, Tubing, Hoses, & Adaptors – Sterile and Non-Sterile	Electrosurgical pencils, Tubing, Hoses, & Adaptors – Sterile and Non-Sterile
Materials of Construction	Stainless Steel Housing, Insulation, Glass micro fiber filter media, granular activated carbon	Coated Aluminum Housing and ABS Plastic Fascia, Insulation , Glass micro fiber filter media, coconut shell carbon	Powder-Coated Aluminum Housing , ABS –PC Plastic Fascia, Insulation, Glass micro fiber filter media, granular activated carbon
Specifications	Flow Up to 60 CFM, Filter Efficiency of 99.99995% at 0.12 microns	Flow up to 25 CFM, ULPA Filter Efficiency of 99.9995% at 0.12 microns or greater	Flow up to 30 CFM, Filter Efficiency of 99.999% at 0.1 to 0.2 microns
Device Mechanism of Action	Vacuum source with a mechanical means of filtration	Vacuum source with a mechanical means of filtration	Vacuum source with a mechanical means of filtration
Air Flow Path	Through Vacuum hose or tubing, into a filter, then vacuum motor, and vented into the room	Through Vacuum hose or tubing, into a filter, then vacuum motor, and vented into the room	Through Vacuum hose or tubing, into a filter, then vacuum motor, and vented into the room
Performance	25 Hours filter life, capture and filtration of smoke plume at 99.99995% efficiency	The ULPA-grade filter is 99.9995% efficiency at 0.12 micron particle size with a filter life of up to 35 hours	The ULPA-grade filter is 99.999% efficiency at 0.10 to 0.20 micron particle size with a filter life of up to 35 hours
Human Factors	Used by surgeons and trained health care professionals	Used by surgeons and trained health care professionals	Used by surgeons and trained health care professionals
Electrical Safety	Tested and Compliant to IEC 60601-1:1990	IEC 60601-1 tested and compliant	Tested and Compliant to IEC 60601-1 and IEC 60601-1-2
Mechanical Safety	Tested and compliant per IEC60601-1 for mechanical safety	Tested and compliant per IEC60601-1 for mechanical safety	Tested and compliant per IEC60601-1 for mechanical safety
Chemical Safety	Neutral pH, non-patient contact	Neutral pH, non-patient contact	Neutral pH, non-patient contact

Thermal Safety	Operation of the device does not result in harmful temperatures, tested and compliant per IEC60601-1	Operation of the device does not result in harmful temperatures, tested and compliant per IEC60601-1	Operation of the device does not result in harmful temperatures, tested and compliant per IEC60601-1
Radiation Safety	Non-radioactive	Non-radioactive	Non-radioactive

The design, operational and technical characteristics, performance and non-clinical testing of the VISICLEAR smoke evacuation system are substantially equivalent to and as effective as that of the predicate devices.

The differences noted in the chart between the VISICLEAR smoke evacuation system and the listed predicates are the filter life performance and maximum air flow performance. Testing has demonstrated the VISICLEAR system operates as effective as the listed predicate devices.

The VISICLEAR is as safe and performs as well as the previously identified legally marketed predicate devices. The VISICLEAR's intended use and indications statement for use are substantially supported by the previously cleared predicate devices; and do not impact the safety and effectiveness of the device when used as labeled.

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

March 3, 2014

Buffalo Filter, LLC
Ms. Carrie Termin
Director of Quality and Regulatory Affairs
5900 Genesee Street
Lancaster, NY 14086

Re: K131402
Trade/Device Name: VISICLEAR Smoke Evacuation System
Regulation Number: 21 CFR 878.5070
Regulation Name: Air Handling Device for a Surgical Operating Room
Regulatory Class: II
Product Code: FYD
Dated: January 17, 2014
Received: January 24, 2014

Dear Ms. Termin:

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.

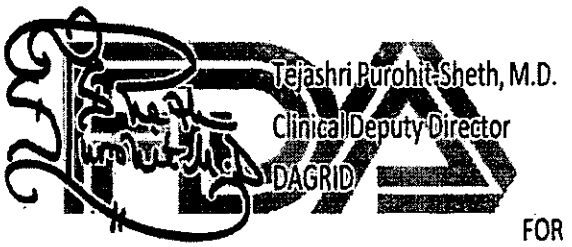
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



FOR

Erin I. Keith, M.S.
Acting 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

510(k) Number: K131402

Device Name: VisiClear Smoke Evacuation System

Indications For Use:

The VisiClear Smoke Evacuation System is designed to remove and filter smoke and aerosols from a surgical site produced during electrosurgical and laser procedures

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

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.02.28 11:45:19 -05'00'