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

June 10, 2015

Buffalo Filter, LLC
% Mr. Dave Yungvirt
Third Party Review Group
45 Rockefeller Plaza, Suite 2000
New York, New York 10111

Re: K150569
Trade/Device Name: LaparoVue
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, OCT
Dated: May 27, 2015
Received: June 1, 2015

Dear Mr. Yungvirt:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150569

Device Name
LaparoVue

Indications for Use *(Describe)*

LaparoVue is a single-use, sterile device to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For
LAPAROVUE

Submitter:

Buffalo Filter, LLC
5900 Genesee Street
Phone: (716)835-7000
Fax No: (716)835-3414
FDA Registration number: 1319744

Contact: Pamela Netzel
Director of Quality & Regulatory Affairs
Telephone: (716) 835-7000
Fax No: (716) 835-3414

Prepared Date: 28 May, 2015

1. Device Name

Trade Name:	LaparoVue, model LapVue01
Common/Usual Name:	Endoscope Anti-Fogging Device
Classification Name:	Endoscope and / or accessories (21 CFR 876.1500, Product Code: GCJ (primary), OCT (secondary)

2. Predicate Device

Buffalo Filter claims substantial equivalence to:

New Wave Surgical Corporation. Defogging Heated Endoscope Lens Protector (D.H.E.L.P.) K062779

3. Description of Device

The LaparoVue is designed as an accessory to be used prior to and during procedures that utilize a laparoscope or endoscope. It is designed to warm the scope above body temperature and apply a warmed surfactant. The device is provided sterile (radiation) and intended for single-use only in a healthcare facility / hospital.

The thermodynamic principle of placing a cold instrument into contact with warm, moist air results in condensation, or more commonly referred to as fogging. The LaparoVue provides the user the ability to warm the endoscope or laparoscope to a temperature very similar to what is found in the human body to mitigate the large temperature change, thus preventing the condensation, or fogging, of the lens when placed into that environment.

The LaparoVue is activated by the user removing the nonconductive slip sheet from the bottom, completing the battery circuit. Once activated, internal circuitry begins the warming function of the device. The user is alerted to this activation by LEDs which are illuminated at each port. The LaparoVue has two ports that accept endoscopes and/or laparoscopes ranging from 3mm to 12mm in diameter. The horizontal port is the main warming port, primarily used prior to the surgical case to warm the scope before the insertion into a body cavity. A small scope stand is part of the LaparoVue, designed to support the main axis of the scope, allowing it to rest horizontally on a flat stable surface. The vertical port contains a sponge that is saturated with the surfactant solution and warmed when the device is active. This port allows for the user to apply the warmed surfactant prior to and during the case.

The LaparoVue is powered by alkaline batteries and has a single-use surgical life of a minimum of 5 hours.

A small piece of microfiber is attached to the main housing of the unit that would allow the user to physically wipe the lens to remove any debris throughout the surgical procedure.

The VueTip trocar swabs are an accessory that is provided in the same package with the LaparoVue. They are each a sterile, single-use accessory to be used to physically clean debris from the trocar/cannula to minimize any smudging of the scope lens when it is inserted. The trocar swabs are constructed using foam attached to a handle, where the foam is used for the mechanical wiping of the port of the trocar/cannula. Two different configurations are provided, one with a foam diameter intended for use with trocar/cannulas up to 7mm, and the other for trocar/cannula with a diameter from 7mm up to 12mm. The handle material for the VueTip trocar swab is constructed to be radiopaque for the surgical setting.

A microfiber cloth is an accessory that is provided in the same package with the LaparoVue. The cloth is a sterile, single-use accessory to be used as an alternate method to physically wipe debris from the lens of scope during the case. The construction of the microfiber cloth is radiopaque for the surgical setting.

4. Intended Use

The LaparoVue is designed for general minimally invasive surgery that utilizes a camera system for visualization into a body cavity. The LaparoVue enables the operator to warm the camera prior to and throughout the surgical case, along with applying a warmed surfactant to lens prior to insertion into the surgical field.

Indications for Use:

LaparoVue is a single-use, sterile device to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

5. Description of Safety and Substantial Equivalence

Minimally invasive surgery and the use of a laparoscope or endoscope for visualization during those procedures is the primary market for both the subject and predicate devices. The prevention of the condensation of moisture on the viewing lens of the scope is the technological principle for both the subject and predicate device.

At a high level, the subject and predicate devices are based on following same technological elements:

- Heat transfer – used to warm the scope to a similar temperature as the target surgical environment
- Surfactant solution – warmed to aid in transfer of heat to lens
- Single-use, sterile device to be used during a single surgical procedure

- Battery power – used to produce the heat to warm the scope
- LED light – used to notify the user the device is active

The following technological differences exist between the subject and predicate device:

- Multiple ports - for warming a scope prior to or during a procedure
- Scope stand – designed to support main axis of the scope, allowing it to rest on a flat, stable surface
- Activation – removal of a non-conductive slip sheet to complete battery circuit and activate the device

6. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the LaparoVue was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The battery of testing included the following tests:

- Cytotoxicity
- Systemic Toxicity
- Maximization Sensitization
- Intracutaneous Sensitization

The LaparoVue and its accessories are considered an external device that contacts the Tissue / bone / dentin for a limited contact duration (less than 24hrs).

Sterilization Testing

Sterilization validation testing completed using Method 1 as detailed in AAMI/ANSI/ISO 11137-2. Bioburden and sterility testing were performed in accordance with FDA recognized consensus standard AAMI/ANSI/ISO 11737-1 and AAMI/ANSI/ISO 11737-2.

The packaging configuration was sterilized and subjected to transportation condition. Testing was then performed to confirm package integrity and seal

strength post conditioning to ensure products remain sterile, according to ASTM F2096-11.

Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LaparoVue. The system complies with IEC 60601-1 standard for safety and IEC 60601-1-2 standard for EMC.

Performance Testing – Bench

The following bench tests were performed for this submission:

Life Expectancy Verification

Life expectancy bench testing was performed to verify the device operates for the labeled (5) five hours. The device was activated and the temperatures at multiple points, including the scope body were recorded to ensure the warming operation demonstrated no change in performance over the labeled use of the product.

Lens Fogging Validation

Lens fogging bench testing was performed to verify the effectiveness of the device at preventing the lens from fogging when inserted into a simulated laparoscopic environment. Using calibrated equipment, a laparoscope was warmed per the directions for use and then inserted into a chamber with a similar environment with regards to temperature and humidity as found during actual use. The testing utilized actual laparoscopic equipment and digital images were recorded to demonstrate the effectiveness of preventing the fog from forming on the lens when the LaparoVue was utilized.

Performance Testing – Animal

No animal testing was conducted for this submission

Performance Testing – Clinical

No clinical testing was conducted for this submission

7. Conclusion

The design, operational and technical characteristics, performance and non-clinical testing of the LaparoVue are substantially equivalent to that of the predicate device.