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

May 18, 2017

Buffalo Filter, LLC
% Mark A. Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO, MN 55313

Re: K171139
Trade/Device Name: LaproLight™ Veress Needle
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: Unclassified
Product Code: HIF
Dated: April 17, 2017
Received: April 18, 2017

Dear Mark A. 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 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K171139

Device Name
LaparoLight™ Veress Needle

Indications for Use *(Describe)*

The LaparoLight™ Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

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.

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510(k) Summary
For
LAPAROLIGHT™ VERESS NEEDLE

Submitter:

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Prepared Date: March 20, 2017

1. Device Name

Trade Name: LaparoLight™ Veress Needle, models LLVN12001 and LLVN15001

Common/Usual Name: Veress Needle

Classification Name: Insufflator, Laparoscopic (21 CFR 884.1730, Product Code: HIF and FHO

2. Predicate Device

Buffalo Filter claims substantial equivalence to:

Unimax Medical Systems Inc, Unimax Veress Needle (K111441)

This predicate device has not been subjected to a design-related recall.

3. Description of Device

The LaparoLight™ Veress Needle is a Veress needle that includes an LED indicator. This product is used to establish pneumoperitoneum prior to start of laparoscopic procedure. LaparoLight™ Veress Needle is available in two lengths: 120mm and 150mm to use in different size patients and applications. LaparoLight™ Veress Needle is provided sterile and intended for single-use only in a healthcare facility/hospital.

LaparoLight™ Veress Needle includes a spring loaded blunt stylet mechanism. When pressure is applied on blunt tip, it retracts and allows the sharp edge of cannula to cut through the tissue. Product also includes a slip sheet which when pulled activated the LED indicator. LED will turn ON and stay ON as long as the blunt tip of the product is extended forward past sharp edge of cannula. Thus during the puncture of peritoneum wall the LED will turn OFF while there is a pressure against blunt tip and turn back ON when cannula has entered a cavity allowing the blunt tip to spring forward.

In addition LaparoLight™ Veress Needle includes a luer lock for syringe connection to perform saline flow test and insufflation tubing for gas delivery. Stop cock is present downstream of luer lock to control the flow of liquid or gas through the needle with possible positions ON and OFF.

4. Intended Use

The LaparoLight™ Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

5. Description of Substantial Equivalence

The subject and predicate device have the same intended use.

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

- Spring loaded blunt stylet – used to protect internal organs from sharp of cannula.
- Blunt tip exposure indicator – an indicator that shows to the user if blunt tip is extended or retracted
- Luer Lock – connection point for syringe to perform saline test and insufflation tubing for CO2 gas delivery
- Stop Cock – to control gas passage through the needle

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

- Type of Blunt tip exposure indicator – LaparoLight™ Veress Needle contains an LED instead of a red marker painted on the needle hub that shows if blunt tip is extended
- Slip Sheet – for product activation prior to use

The differences in technology do not raise different questions of safety and effectiveness.

6. Performance Data

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

Biocompatibility Testing

The biocompatibility evaluation for the LaparoLight™ Veress Needle was conducted in accordance with 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:

- In Vitro Cytotoxicity
- Maximization Sensitization
- Intracuteneous Reactivity
- Systemic Toxicity Testing
- Rabbit Pyrogen Testing

The LaparoLight™ Veress Needle is considered a device that contacts the Tissue / bone / dentin for a limited contact duration (less than 24hrs). The test results demonstrate that the subject device is biocompatible.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the LaparoLight™ Veress Needle. The system complies with AAMI/ANSI ES 60601-1:2005/(R)2012 And A1:2012 standard for electrical safety and IEC 60601-1-2 Edition 4.0 2014-02 standard for EMC.

Performance Testing – Bench

The following bench tests were performed for this submission, and the subject device passed all tests.

- LaparoLight™ Veress Needle Design Validation

  Design Validation was performed to verify that the LaparoLight™ Veress Needle product can operate as intended. Validation test included puncturing of simulated tissue, operation of blunt tip position indicator, saline and gas delivery.

- LaparoLightTM Veress Needle Force Equivalency

  Force testing was conducted to confirm that the force of the spring loaded blunt stylet and puncture force are similar to the predicate device

- LaparoLight™ Veress Needle Tip Pull Test

  Testing to confirm equivalence to predicate device performance with regard to strength of bond between components

- LaparoLight™ Veress Needle Switch Operation Test

  Testing to confirm equivalence to predicate device performance by testing control of gas flow with stop cock/flow controller assembly

- LaparoLight™ Veress Needle Spring Obturator Operation Test

  Testing to confirm equivalence to predicate device performance – testing covered "click" of the needle and blunt tip extension once the needle enters open internal volume

- LaparoLight™ Veress Needle Puncture Force Test

  Testing to confirm equivalence to predicate device performance – testing covered puncture force required to puncture tissue simulator

7. Conclusion

The performance testing demonstrates that the LaparoLight™ Veress Needle is substantially equivalent to the predicate device.