September 19, 2018

Xodus Medical, Inc.
Mr. Paul Lloyd
Vice President, Global QA/RA & Technology
702 Prominence Drive
New Kensington, Pennsylvania 15068

Re: K182080
Trade/Device Name: Scope Antifogging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, OCT
Dated: July 27, 2018
Received: August 2, 2018

Dear Mr. Lloyd:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182080

Device Name
Scope Antifogging System

Indications for Use *(Describe)*
The Scope Antifogging System is intended use for this device is to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the endoscope and laparoscope 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.

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SECTION 5 - 510(k) Summary

510(k) Owner: Xodus Medical, Inc.
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, PA 15068
Phone: 724-337-5500
Fax: 724-337-1131
Contact: Paul Lloyd (Vice President, Global QA/RA & Technology)

Establishment Registration Number: 2530138

Date Prepared: July 27, 2018

1. **Device Information:**

   Trade/Device Name: Scope Antifogging System
   Common Name: Endoscope Antifogging Device
   Classification Name: Endoscope and/or Accessories
   Regulation Number: 21 CFR 876.1500
   Product Code: GCJ; OCT
   Regulatory Class: II

2. **Legally Marketed Devices to which Xodus Medical claims Substantial Equivalence:**

   Device Name: Clearify Visualization System
   Common Name: Endoscope Antifogging Device
   510(k) Number: K062779
   510(k) Owner: Covidien LLC
   Classification Name: Endoscope and/or Accessories
   Regulation Number: 21 CFR 876.1500
   Product Code: GCJ; OCT
   Regulatory Class: II

   *The Covidien predicate device is formerly known as New Wave Surgical's DHELP, FDA 510k K062779, acquired by Medtronic/Covidien and marketed as Clearify Visualization System under a name change only.

3. Device Description

The Scope Antifogging System is a single use, sterile device that is designed to apply an antifogging solution (surfactant) and warm the scope at or above the human body temperature when used prior to and during procedures that utilize an endoscope or laparoscope.

The Scope Antifogging System provides antifogging of the lens of the endoscope and laparoscope when inserted into the Scope Antifogging System for use in a laparoscopic procedure. Fogging occurs when the ambient temperature of the lens of the endoscope/laparoscope is cooler than the temperature of the human body and condensation forms on the lens. This is especially important in a surgical procedure where a surgeon must have a clear view of the operative site to safely perform surgery.

The Scope Antifogging System is controlled by an on switch to activate the circuit containing battery power source to indicate the activation of the antifogging solution warming circuit. The activation of the warming circuit life expectancy is 5 hours.

The antifogging solution is retained in the device and warmed when the device is activated in the "on" position. Subsequently, the endoscope/laparoscope is inserted into the device port for application of the warmed antifogging solution. The device's single scope insertion port of the endoscope/laparoscope accepts scopes up to 12mm in diameter.

The antifogging solution is included in with the Scope Antifogging System as fluid contained in two separate bottles. The solution is dispensed into the single port opening of the housing of the Scope Antifogging System prior to use.

Included with the Scope Antifogging System in the same packaging is a pair of sponge-tipped, trocar wipes. The trocar wipes are a single-use, radiopaque accessory used to wipe debris from the inside of the trocar during the surgical procedure. The trocar wipe sponge tip diameters are 7mm and 12mm.

Also included with the Scope Antifogging System in the same packaging is a single-use, microfiber cloth. The microfiber cloth is an accessory used as a method to wipe the endoscope/laparoscope lens of any debris buildup.

This product is sold sterile to healthcare professionals only.

The Scope Antifogging System has not been previously submitted for 510(k) clearance. However, the Xodus Medical Scope Antifogging System component, Antifog solution, is also a separately sold product, and is currently marketed by Xodus Medical with FDA clearance under 510k number K063587.

4. Intended Use:

The Xodus Medical Scope Antifogging System intended use is identified to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

5. Indications for Use:

The Scope Antifogging System is a single use, sterile device to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

6. Description of Safety and Substantial Equivalence

The Xodus Medical Scope Antifogging System has the same intended use as the predicate device, Covidien Clearify Visualization System, which is, "Use prior to and during endoscopic and laparoscopic procedures to prevent the fogging of the scope lens". The Xodus Medical Scope Antifogging System and Covidien Clearify Visualization System are based on the same technological elements shown in the table below.

Comparison Table to Predicate Device

Name of Device	Xodus Medical Inc.'s Scope Antifogging System	Covidien's Clearify Visualization System
Intended Use	Scope Antifogging System intended to be used prior to and during endoscopic and laparoscopic procedures to prevent the fogging of the scope lens.	Clearify Visualization System intended to be used prior to and during endoscopic and laparoscopic procedures to prevent the fogging of the scope lens.
Usage	Hospitals and/or surgery centers on or by the order of a physician	Hospitals and/or surgery centers on or by the order of a physician
Materials	Antifogging Solution: Water, Isopropanol, Ethanol, Surfactant. Material difference in housing using polycarbonate plastic.	FDA approved ShurClens, a wound cleaning surfactant; Water, alcohol, and surfactant. Material difference in housing using polyurethane foam.
Physical Characteristics	Antifogging Solution of Clear/ colorless, odorless, water soluble liquid. Similar physical footprint-Xodus lower profile; Shape is triangular design.	Antifogging Solution of Clear/ colorless, odorless, water soluble liquid. Physical footprint with rounded, oval design, higher profile.
Sterilization	Gamma radiation	Gamma radiation
Design/Packaging	Sterile barrier of polyethylene plastic and Tyvek	Sterile barrier of polyethylene plastic and Tyvek
Mechanism of Action	Heating and dipping of distal end of endoscope/laparoscope into solution	Heating and dipping of distal end of endoscope/laparoscope into solution
Biocompatibility Standards Compliant	Yes, per ISO 10993-1	Yes
Target Population	Physicians, Nurses, Health Care Professionals, General Surgery	Physicians, Nurses, Health Care Professionals, General Surgery
Power Source	Battery	Battery
Single Use	Yes	Yes
Sterility	Sterile	Sterile
510(k) Number	TBD	K062779

7. Performance Data:

7.1 Performance Testing – Bench

The following bench tests were performed for this submission:

7.1.1 Scope Lens Fogging Validation:

Lens fogging validation testing was performed using the Xodus Medical Scope Antifogging System and the predicate device. The testing performed was to verify the effectiveness of the Scope Antifogging System at preventing fogging from occurring on simulated equipment. A laparoscope and a glass mirror plate were used in the testing and subjected to a high humidity source. Using a control, the antifogging solutions of both products were applied to the simulated equipment, the laparoscope and glass mirror plate. The testing conclusions were the Xodus Medical Scope Antifogging System demonstrated the effectiveness of preventing the fogging of the simulated equipment consistently, as with the predicate device.

7.1.2 Life Expectancy Validation

Testing of the duration of activation of the warming circuit was performed. The Scope Antifogging System was activated and observed for duration of the activation period. Thermal characteristics were observed during the activation period and determined the activation to be a minimum for five (5) hours.

7.1.3 Trocar Wiping Validation

Testing of the wiping of the inside of the trocar to clear any debris following application of blood and tissue (general smudging) from beef liver and extracting the scope was conducted.

The blood and tissue were applied to the scope interior of the trocar and successfully wiped away on three test cases using the trocar wipes of the Scope Antifogging System and the Covidien Clearify Visualization system trocar wipes. There were no visible signs of any debris left behind following the wiping of the inside of the trocar.

7.2 Performance Testing –Animal

The following animal tests were performed for this submission:

7.2.1 Scope Lens Fogging Validation

Testing of the Xodus Medical Scope Antifogging System and the predicate device was conducted with a live, anesthetized pig. A Karl Storz endoscopy system was used with a 5mm and 10mm Storz laparoscope. A

series of exploratory procedures with four different Storz laparoscope types were used. Cleaning and application of antifogging solution to the scopes for determination of fogging prevention was performed in several instances. In all cases, the Scope Antifogging System demonstrated effectiveness of preventing the fogging of the laparoscopes consistently, as with the predicate device.

7.2.2 Scope Lens Wiping of Debris Validation

Testing of the wiping of the scope lens following application of bile, blood, and tissue was conducted. The matter was applied to the scope lens and subsequently successfully wiped away successfully on all occasions using the microfiber cloth and the foam pad on the Scope Antifogging System.

7.3 Biocompatibility

The Scope Antifogging System was successfully conducted to the ISO 10993-1 standard, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a Risk Management System". The biocompatibility tests performed are shown below. These tests were determined to be applicable to the product according to the device classification according to ISO 10993-1 Appendix A, Table A.1.

The product category was determined to be "External Communicating Device"; Contact determined to be "Tissue/Bone/Dentin; with Contact Duration "A-limited, ≤24hr"; and Biological Effect determined to be "Cytotoxicity, Sensitization, and Intracutaneous Reactivity". Additional biocompatibility tests included were include in the biocompatibility testing, the Acute Systemic Toxicity, and Pyrogenicity.

7.4 Sterilization

The Scope Antifogging System shall be sterilized by gamma radiation based on the ISO 11137-2 standard; "Sterilization of Health Care Products – Part 2: Establishing the Sterilization Dose". The process shall be validated to ensure 10^{-6} sterility assurance or better is achieved.

The sterilization shall follow the same processes as currently marketed Xodus Medical FDA 510(k) cleared sterile products to include Antifog Solution 510(k) K063587, ES Pencils and Electrodes 510(k) K081647; Cautery Tip Cleaner 510(k) K053433, and Light Guard Light Handle 510(k) K053321.

7.5 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC compatibility testing was successfully conducted on the Scope Antifogging System. The system complies with the IEC 60601-1-2 standard for EMC.

The Scope Antifogging system shall be electrical safety tested to the standard IEC 60601-1.

8. Conclusion:

The design, characteristics, and performance of the Scope Antifogging System substantiate that the device is working as intended (use prior to and during endoscopic and laparoscopic procedures to prevent the fogging of the scope lens). The Xodus Medical Scope Antifogging System is substantially equivalent to its predicate device, Covidien's Clearify Visualization System.