February 17, 2023

Biotex Inc.
Wade Munsch
Regulatory Affairs Manager
114 Holmes Rd.
Houston, Texas 77045

Re: K222695
Trade/Device Name: troCarWash™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX, FEQ
Dated: September 2, 2022
Received: January 18, 2023

Dear Wade Munsch:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.02.17 09:01:18 -05'00'

On behalf of
Long Chen, Ph.D.
Assisstant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222695

Device Name

troCarWash™ System

Indications for Use *(Describe)*

The troCarWash™ system consists of a reusable control unit and a disposable, sterile, single-use trocar intended to remove visual obstructions such as condensation, blood, and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintain a clear image of the surgical site.

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) #: K222695

510(k) Summary

Prepared on: 2023-01-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biotex, Inc.
Applicant Address	114 Holmes Rd. Houston TX 77045 United States
Applicant Contact Telephone	7137410111 x208
Applicant Contact	Mr. Wade Munsch
Applicant Contact Email	wade.munsch@biotexmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	troCarWash™ System
Common Name	Endoscope and accessories
Classification Name	Endoscopic Irrigation/Suction System
Regulation Number	876.1500
Product Code	OCX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171637	OpClear System	OCX
K190029	Disposable Bladeless Trocar, Disposable Optical Trocar, Disposa	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The troCarWash™ system is a laparoscopic lens cleaning device which is intended to be used during any laparoscopic surgical procedure where there is a potential for contamination of the distal lens of the laparoscope. Consisting of a mains powered reusable control unit, and a single use disposable trocar, obturator, and tubing set, it is intended to maintain surgical vision by removing contaminants such as condensation, blood, peritoneal fluid, smoke, fat, and tissue smears that have contaminated the distal lens of the laparoscope during surgical procedures providing a clear image of the surgical site. The disposable portion of the system is sterilized via irradiation and has limited (<24 hours) patient contact with abdominal tissue. The trocar and obturator are primarily made of ABS and polycarbonate, and the tubing set is made of ABS, Polycarbonate, and PVC tubing. The system is intended for use in typical hospital environments by medical professionals and is suitable for all patients approved for laparoscopic operations. The system incorporates a software that initiates a short (<250 millisecond) wash and dry mechanism to efficiently clean the lens of the laparoscope and may be initiated with a natural single-handed surgical motion of retracting the scope momentarily into the supplied trocar.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The troCarWash™ system consists of a reusable control unit and a disposable, sterile, single-use trocar intended to remove visual obstructions such as condensation, blood, and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintain a clear image of the surgical site.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use between the predicate device and the subject device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The troCarWash™ System is substantially equivalent to the OpClear System. Both the subject device and the predicate device have the same intended use and are used for the same indications. Specifically both devices are intended to remove visual obstructions such as condensation, blood, and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintaining a clear image of the surgical site. In addition, both the subject device and the predicate device use medical grade CO2 and saline to clear the lens of debris. The technical differences between the subject device and the predicate device consist of the following:

- The subject device only has one mode to clean. It does not incorporate a foot pedal but instead uses a light sensor to detect the position of the scope as the user pulls the scope back within the trocar to deliver a cleaning cycle.
- The subject device utilizes a trocar-based wash apparatus in lieu of a sheath which is designed to fit all 10mm scopes regardless of brand or angle.
- Having the wash apparatus built into the trocar eliminates the need to potentially upsize the trocar due to an increased diameter of the laparoscope when used with a sheath and potentially obstruct visualization from the sheath.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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

Packaging Validation

Packaging validation testing was completed per the listed standards:

- ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1980 Standard Guide for Accelerate Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4332: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607 – 1 Packaging of Terminally Sterilized Medical Devices – Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 16269-6 Statistical Interpretation of Data – Part 6 Determination of Statistical Tolerance Intervals

The troCarWash™ system passed the seal strength and package integrity testing for environmental conditioning and simulated T&D, and Accelerating Aging.

Sterilization Validation

Sterilization validation testing was completed per the listed standards:

- ANSI AAMI ISO 11137-1:2006/(R)2010: Sterilization of health care products – Radiation – part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI AAMI ISO 11137-2:2013: Sterilization of health care products – Radiation – Part 2: Establishing the Sterilization Dose
- AAMI/ISO 11737-1:2018: Sterilization of medical devices – Microbiological methods – Part 1: Determination of population of microorganisms on products
- AAMI/ISO 11737-2:2019: Sterilization of a medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation, maintenance of a sterilization process

The troCarWash™ system is sterilized via irradiation. To validate the sterilization cycle, VDmax25 was used, which includes bioburden testing, bioburden recovery, verification dose testing, product sterility testing, and method suitability testing.

Biocompatibility Testing

The troCarWash™ system is a limited (<24 hours) patient contacting device. The trocar, obturator, and tubing set are the only components that contact the patient, while the reusable controller does not have any contact with the patient. The biocompatibility evaluation for the troCarWash™ system included cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated Pyrogenicity. All testing was conducted in accordance with the following standards and guidance documents:

- ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO 10993-12 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
- FDA Guidance Document "Use of international Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process"

Electrical Safety and Electromagnetic Compatibility (EMC and EST)

Electrical safety and EMC testing were conducted on the troCarWash™ system, consisting of the reusable controller and disposable set (trocar, obturator, and tubing set). The system complies with the IEC 60601-1, IEC 60601-1-6, and IEC 60601-2-18 for EST and IEC 60601-1-2 for EMC.

Software Verification and Validation Testing
Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since a failure or latent flaw in the system would not result in injury or damage to health.

Bench Performance Testing
Performance Testing was conducting in a benchtop model to evaluate system performance. 29 disposable sets (trocar, obturator, and tubing set) preconditioned with sterilization and accelerated aging and 8 disposable sets preconditioned with sterilization and simulated transportation and distribution were tested for wash efficacy. The study demonstrated that with various scope angles and brands, the troCarWash™ system was able to achieve acceptable cleans.

No clinical data was necessary to support a claim of substantial equivalence.

The troCarWash System performance testing demonstrated a sufficient wash efficacy across scope angles tested. The risk controls and bench performance testing ensure the troCarWash system raises no new issues of safety or effectiveness. The descriptive information contained within the predicate 510(k) is sufficiently precise to ensure the substantial equivalence of the troCarWash™ System, and to determine that there are no new issues of safety or effectiveness. There is no need for comparative performance data as the effect of the device in terms of cleaning and defogging the lens is demonstrated through the bench performance testing.