July 7, 2022

JDI Surgical, Inc.
% Srividya Pothana
Regulatory Affairs Associate
University of Utah
10 North 1900 East, EHSL Rm. 22B
Salt Lake City, Utah 84112

Re: K221293
Trade/Device Name: E-Brik Visualization Assistant
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, OCT
Dated: May 2, 2022
Received: May 4, 2022

Dear Srividya Pothana:

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,

for

Long Chen, Ph.D.
Assistant 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.

510(k) Number *(if known)*

Device Name
E-Brik Visualization Assistant

Indications for Use *(Describe)*

The E-Brik Visualization Assistant is intended 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.

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JDI Surgical

510(K) SUMMARY

(21 CFR 807.92)

GENERAL INFORMATION

Submitter: JDI Surgical, Inc.

Contact Person: Srividya Pothana, MS – Regulatory Affairs Associate
University of Utah/ Center for Medical Innovation
10 North 1900 East, Rm. 22B
Salt Lake City, UT 84112
(801) 587-1456
sri.pothana@utah.edu

Date Prepared: May 02, 2022

Trade Name: *E- Brik* Visualization Assistant, Model EBK100

Common Name: Endoscopes Anti-Fogging Device

Classification Name: Endoscopes and Accessories
21 CFR §870.1500, Product Code GCJ & OCT

Device Class: Class II

Predicate Device: 510(k) No.: K150569
Model: LaparoVue
Manufacture: Buffalo Filter, LLC
Classification: GCJ & OCT

Device Description:
The E-Brik™ Visualization Assistant 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 and is intended for single use only in a healthcare facility/ hospital.

The E-Brik™ 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 an LED which is illuminated below both ports. The E-Brik™ has two ports that accept endoscopes and/or laparoscopes ranging from 3mm to 10mm in diameter. Both ports can be used prior to the surgical case to warm the

scope(s) before the insertion into a body cavity. The E-Brik™ can act as a scope stand as it is designed to support the main axis of the scope, allowing it to rest horizontally on a flat stable surface. A sterile surfactant solution is added to the ports prior to use, which is warmed when the device is active. The ports allow for the user to apply the warmed surfactant prior to and during the case.

The E-Brik™ is powered by alkaline batteries and has a single-use surgical life of a minimum of 4 hours.

Intended Use:
The E-Brik™ is designed for general minimally invasive surgery that utilizes a camera system for visualization into a body cavity. The E-Brik™ enables the operator to warm the camera prior to and throughout the surgical case, along with applying a warmed solution (i.e., sterile water) to lens prior to insertion into the surgical field.

Indications for Use:

The E-Brik™ Visualization Assistant is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Comparative Analysis:

It has been demonstrated that the E-Brik™ is comparable to the predicate device in fundamental scientific technology, design, materials, principles of operation and functional performance evaluations and is substantial equivalent as summarized in **Table 1**. Furthermore, the E-Brik™ system has been fully assessed within the JDI Surgical Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm substantial equivalence. The differences raise no additional or different questions of safety or effectiveness from that already identified for the predicate device.

It has been demonstrated that the E-Brik™ system is comparable to the predicate device in the following manner:
• Same intended use
• Same indications for use
• Same fundamental scientific technology
• Same or similar material properties
• Same operating principle
• Same or similar performance specifications
• Same or similar patient-user interface

JDI Surgical

510(k) Summary

Table 1: Substantial Equivalence Comparison Chart		
	Subject Device – *E-Brik*™	**Predicate – K150569 LaparoVue**
Ind. for Use	The E-Brik™ is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.	The LaparoVue is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.
Endoscope size accommodated	3mm - 10mm	3mm - 12mm
Solution	Sterile water added by the user	Surfactant solution
Sponge	No Sponge	Yes
Mechanism of Action	Heating & dipping distal end of endoscope into solution.	Heating & dipping distal end of endoscope into solution.
Number of Ports	2	2
Classification Name	Endoscopes and Accessories - Endoscope Anti-fogging Device 21 CFR §870.1500 Product Code: GCJ & OCT Class II	Endoscopes and Accessories - Endoscope Anti-fogging Device 21 CFR §870.1500 Product Code: GCJ & OCT Class II
Reuse/ Disposable	Single use disposable	Single use disposable
Accessories	None Provided	Microfiber cloth & Swab
Prescription (Rx Only)	Yes	Yes
Contains Batteries	Yes	Yes
Battery Activation	Remove non-conductive slip sheet	Remove non-conductive slip sheet
LED Light	Notify the user the device is active	Notify the user the device is active
Sterility	Sterile-Gamma	Sterile – Gamma
Biocompatibility Classification	External device, indirect tissue contact, limited duration (<24 hr)	External device, indirect tissue contact, limited duration (<24 hr)
Biocompatibility	ISO 10993	ISO 10993

Functional/Safety Testing:
Verification activities were performed on the subject E-Brik™ to demonstrate substantial equivalence to the predicate device:

- **Biocompatibility** – Biocompatibility of the complete and finished E-Brik™ system has been verified according to the requirements and testing prescribed in ISO 10993-1 and

in accordance with FDA guidance document “Use of International Standard ISO 10993-1” for an external communicating device with indirect tissue contact for a limited duration (<24hrs). Per ISO 10993-1, testing included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

- **Design Verification** – Performance bench testing was conducted to ensure that the E-Brik™ system met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate device. The following performance testing was performed or fulfilled with the E-Brik™ system.
  - **Sterilization** – Testing was conducted to demonstrate that the E-Brik™ system could be sterilized via Gamma radiation to a SAL level of 10^{-6}.
  - **Packaging** – Sterile barrier meet or exceeded the ISO 11607, ASTM D4169, and ISTA IIIA requirements.
  - **Electrical Safety and Essential Performance Requirements** – Testing was conducted on the E-Brik™ system for compliance with IEC 60601-1 - Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
  - **Electromagnetic Compatibility (EMC)** – Testing was conducted on the E-Brik™ system for compliance with IEC 60601-1-2/ EN 60601-1-2 – Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
  - **Performance Testing – Bench** – The testing was completed based design and risk-based requirements. All testing passed.
  - **Performance Testing – Animal** – No animal testing was conducted for this submission
  - **Performance Testing – Clinical** – No clinical testing was conducted for this submission

Conclusion:
The subject E-Brik™ Visualization Assistant system is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device. The minor differences between the subject E-Brik™ and the predicated device has no effect on safety or effectiveness, as established through various performance tests.