January 12, 2024

TauTona Group Research & Development, Co. LLC
Michael Blanchette
Chief Operating Officer
604 Fifth Ave Suite D
Redwood City, CA 94063

Re: K233020
Trade/Device Name: TauTona Pneumoperitoneum Assist Device (TPAD)
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: December 8, 2023
Received: December 11, 2023

Dear Michael Blanchette:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K233020

Device Name
TauTona Pneumoperitoneum Assist Device (TPAD)

Indications for Use *(Describe)*
The TauTona Pneumoperitoneum Assist Device (TPAD) is intended for use in the upper left quadrant of the abdominal wall (i.e., Palmer's Point) with a Veress needle for the establishment of a pneumoperitoneum 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

SUBMITTER INFORMATION

Applicant:	TauTona Research and Development Group, LLC
Contact:	Mike Blanchette
Phone:	650-503-8250
Email:	mblanchette@tautonagroup.com
Address	604 Fifth Ave, Suite D Redwood City, CA 94063

CORRESPONDENT INFORMATION

Contact:	Joshua Crist
Title:	Regulatory Consultant- Medical Device
Firm:	Biologics Consulting Group

DATE PREPARED: 01/09/2024

DEVICE INFORMATION

Device Name:	TauTona Pneumoperitoneum Assist Device (TPAD)
Common Name:	Laparoscopic insufflator
Regulation Number:	884.1730
Regulation Name:	Laparoscopic insufflator
Product Code:	HIF
Regulatory Class:	Class II

PREDICATE DEVICE INFORMATION

Device Name:	Aragon Surgical LapCap
510(k) Number:	K070651
Manufacturer:	Aragon Surgical Inc.

The predicate device has not been subject to a design related recall.

510(K) SUMMARY

DEVICE DESCRIPTION

The TauTona Pneumoperitoneum Assist Device (TPAD) is a single use device used during laparoscopic surgical procedures. The device consists of a pad which contains an array of suction cups on one side; a port that attaches to a standard hospital vacuum line; a button to control vacuum to the suction cups; and a handle to allow user to manipulate the device. Suction is applied to the device to allow the user to manipulate (hold and pull on) the tissue around the Veress needle insertion site. The device is crescent in shape to allow removal of the device after use while the Veress needle remains in the patient.

INDICATIONS FOR USE

The TauTona Pneumoperitoneum Assist Device (TPAD) is intended for use in the upper left quadrant of the abdominal wall (i.e., Palmer's Point) with a Veress needle for the establishment of a pneumoperitoneum during laparoscopic procedures.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Comparator Table for Subject and Predicate Devices

	Subject Device **TauTona Pneumoperitoneum Assist Device (TPAD)**	**Predicate Device** **Aragon Surgical LAPCAP K070651**	**Comparison**
Product Code	HIF	HIF	Same
Regulation Number	884.1730	884.1730	Same
Regulatory Class	II	II	Same
Indications for Use	The TauTona Pneumoperitoneum Assist Device TPAD is intended for use in the upper left quadrant of the abdominal wall (i.e., Palmer's Point) with a Veress needle for the establishment of a pneumoperitoneum during laparoscopic procedures.	The Aragon Surgical LapCap is intended for use in the peri-umbilical region of the abdominal wall with a Veress needle for the establishment of a pneumoperitoneum during gynecologic (pelvic) and general surgical (intraabdominal) laparoscopic procedures.	Similar indications for use. TPAD Location for use is for Palmers Point Access.
Veress Needle Insertion	Use of negative pressure to attach to skin to support Veress needle insertion. Device can be	Use of negative pressure to attach to skin to support Veress needle insertion. Device is removed with Veress Needle.	Same operating principle. Different removal requirements.

510(K) SUMMARY

	Subject Device **TauTona Pneumoperitoneum Assist Device (TPAD)**	Predicate Device **Aragon Surgical LAPCAP K070651**	**Comparison**
	removed while Veress Needle is in place.		
Vacuum Application	Array of suction cups	Large polycarbonate dome	Similar, the minor differences are supported by both bench and clinical data.
Vacuum Source	External – Hospital Vacuum Line	External – Hospital Vacuum Line	Same
Software/Electronics	None	None	Same
Biocompatibility	Biocompatibility testing in accordance with ISO 10993-1	Biocompatibility testing in accordance with ISO 10993-1	Same

Both devices use negative pressure to attach to skin and support Veress Needle insertion. The subject device, however, applies the vacuum with a design that allows removal of the device after Veress Needle insertion.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

Studies were performed and confirmed that the Subject device is biocompatible for the intended patient contact profile in accordance with ISO 10993-1.

Electrical Safety

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The subject device contains no software.

Performance Testing

Other performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Dimensional testing for vacuum line compatibility, device features
- Vacuum control /holding forces.

510(K) SUMMARY

- Tensile strength
- Shelf-Life

Clinical Data

A randomized clinical study consisting of two arms was performed at an academic center in the U.S. The purpose of this study was to evaluate the safety, effectiveness and ease of use of the TPAD for laparoscopic surgery when the Veress Needle was used to establish pneumoperitoneum. Study population included 20 individuals greater than 18 years old (age range 25 – 73 years old), with a BMI < 35 kg/m2 (range 21.6 – 34.8) requiring a laparoscopic surgery. Other demographics in the study included 55% white, 40% Hispanic/Latino and 5% Asian: 3 biological males and 7 biological females in the TPAD arm, while 5 biological males and 5 biological females were in the Standard of Care (SOC) arm. Ten (10) patients underwent laparoscopic surgery as otherwise planned, with their surgeon using the TPAD device to assist in placement of the Veress needle. Ten (10) additional patients underwent laparoscopic surgery following the SOC. Surgeons completed a questionnaire following the procedures to evaluate the device feasibility/ ease of use. All patients also completed surveys to assess patient satisfaction. The primary endpoint was device feasibility as measured by a surgeon questionnaire completed at the end of every surgery. Secondary endpoints included the time needed to obtain laparoscopic access using the device, time needed to complete insufflation, monitoring for adverse events, time to resolve bruising, and patient satisfaction on skin appearance/bruising as measured by patient surveys and photographs postoperatively. All surgeons were able to place the Veress needle using the TPAD at the 520-mmHg pressure. The surgeon questionnaire answers for both SOC (average range of 3.9 to 4.0) and TPAD (average range of 3.9 to 4.0) had a median of 4.0 for all responses. For all questionnaires, both SOC and TPAD were not significantly different from a theoretical median of 4.0 (Wilcoxon test). Also, the secondary endpoints did not have any statistically significant difference using unpaired t test.

There were no device related serious adverse events (SAEs). All other adverse events were deemed mild and were related to insertion site and skin handling bruising with complete resolution in the TPAD arm as follows: 6/10 subjects' bruising resolved within 3 days, 2/10 subjects between 4 – 6 days, 1/10 subject at 7 days and 1/10 subject at 19 days postoperatively. For the SOC arm bruising resolved within 3 days for 4/10 subjects, between 4 – 6 days for one subject and 5/10 subjects still had bruising at 7+ days postoperatively (one at 7 days, two at 7+ days, one at 8+ days, one at 9+ days and one at 16+ days).

CONCLUSION

The subject device has the same intended use as the predicate, with similar technological characteristics. The differences in technological characteristics do not raise different questions of safety and effectiveness. Performance testing conducted on subject device demonstrate that is as safe and effective as the predicate device to support substantial equivalence.