October 15, 2024

TauTona Group
Mike Blanchette
Chief Operating Officer
604 Fifth Ave
Suite D
Redwood City, California 94063

Re: K242536
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: August 21, 2024
Received: August 26, 2024

Dear Mike 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242536

Device Name
TauTona Pneumoperitoneum Assist Device (TPAD)

Indications for Use *(Describe)*
The TauTona Pneumoperitoneum Assist Device (TPAD) is intended for use with the 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.

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: 10/10/24

DEVICE INFORMATION

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

PREDICATE DEVICE INFORMATION

Device Name:	TauTona Pneumoperitoneum Assist Device (TPAD)
510(k) Number:	K233020
Manufacturer:	TauTona Research and Development Group, LLC

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 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** **TauTona Pneumoperitoneum Assist Device (TPAD)** **K233020**	**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 with a Veress needle for the establishment of a pneumoperitoneum during laparoscopic procedures.	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.	Similar indications for use. Predicate TPAD location for use is for Palmer's Point Access. This 510k is to expand to all regions of the abdominal wall, including Palmer's Point and umbilical regions.
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 can be removed while Veress Needle is in place.	Same

510(k) SUMMARY

	Subject Device TauTona Pneumoperitoneum Assist Device (TPAD)	Predicate Device TauTona Pneumoperitoneum Assist Device (TPAD) K233020	Comparison
	removed while Veress Needle is in place.		
Vacuum Application	Array of suction cups	Array of suction cups	Same
Vacuum Source	External – Hospital Vacuum Line	External – Hospital Vacuum Line	Same
Software/Electronics	None	None	Same
Biocompatible	Biocompatibility testing in accordance with ISO 10993-1	Biocompatibility testing in accordance with ISO 10993-1	Same

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

Performance testing meets its design requirements and performs as intended. This testing is the same as the predicate device. The performance tests include:

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

510(k) SUMMARY

Clinical Data

The clinical study was performed in two phases. The first phase included 20 patients and evaluated the TPAD vs. Standard of Care (SOC) for patients undergoing laparoscopic surgery where the Veress Needle was used to establish a pneumoperitoneum (see K233020). The majority of Veress entries were in the upper left quadrant (i.e. Palmer's point). The second phase of the study included 10 patients and focused on the umbilical region of the abdominal wall. In both phases the studies compared satisfaction, time, and skin impacts. The primary endpoint of the average surgeon questionnaire scoring was not significantly different for SOC and TPAD across all responses. The average timing measurements from the incision to Veress Needle Insertion, as well as time from incision to insufflation, were not significantly different between SOC and TPAD for both timing durations. The average patient questionnaire scoring was not significantly different for SOC and TPAD across all responses. No Severe or Moderate Adverse Events related to the TPAD were observed.

Overall, across this wide range of metrics, the use of TPAD for Veress needle insertion and insufflation was not significantly different than the use of the standard of care for Veress needle insertion and insufflation. These clinical performance data therefore support that the subject device is substantially equivalent to the predicate.

CONCLUSION

The subject device has the same technological characteristics and intended use as the predicate device, with a more general indications for use statement. Clinical testing conducted with the subject device demonstrates that it is as safe and effective as the predicate device to support a substantial equivalence determination.