June 2, 2023

Xpan Inc.
% Michele Lucey
Consultant
Lakeshore Medical Device Consulting, LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K223562
Trade/Device Name: Xpan Universal Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: [NOTE: Use date of most recent supplement]
Received: May 4, 2023

Dear Michele Lucey:

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: 2023.06.02 08:15:43 -04'00'

Mark Trumbore, 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
Xpan Universal Trocar System

Indications for Use *(Describe)*
The Xpan Universal Trocar System is a single use system that is intended to provide dilation access with or without visualization to the abdominal and thoracic cavities for performing diagnostic and operative abdominal and thoracic procedures. The system is indicated for the following uses:

- Laparoscopic access to the abdominal cavity, both primary and secondary punctures.
- Thoracoscopic access to the thoracic cavity, both primary and secondary punctures.

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.

Traditional

510(k) SUMMARY

Submitter:

Applicant	XPAN Inc.
Contact Person	Michele Lucey Lakeshore Medical Device Consulting LLC 603-748-1374 Email: lucey_m@msn.com
Date Prepared	November 17, 2022

Subject Device:

Proprietary/Trade Name	Xpan Universal Trocar System
Common or Usual Name	Surgical Trocar
Classification Name	Endoscope and Accessories
Regulatory Class	Class II
Classification Code	GCJ
Regulation Number	876.1500
Review Panel	General and Plastic Surgery

Predicate Device:

Proprietary/Trade Name	VersaStep™ Bladeless Trocar
510(k) Number	K012539
Common or Usual Name	Surgical Trocar
Classification Name	Endoscope and Accessories
Regulatory Class	Class II
Classification Code	GCJ

	876.1500
Regulation Number	
Review Panel	General and Plastic Surgery

Reference Devices:

Proprietary/Trade Name	GeniCon NanoPort 3mm Trocar
510(k) Number	K982472
Common or Usual Name	Surgical Trocar
Classification Name	Cannula, Surgical
Regulatory Class	Class I (reclassified 2001)
Classification Code	GEA
Regulation Number	876.4800
Review Panel	General and Plastic Surgery
Proprietary/Trade Name	VersaOne 5mm and 12mm Optical Trocars
510(k) Number	K112349, K130435
Common or Usual Name	Surgical Trocar
Classification Name	Endoscope and Accessories
Regulatory Class	Class II
Classification Code	GCJ
Regulation Number	876.1500
Review Panel	General and Plastic Surgery

Intended Use:

The Xpan Universal Trocar System is intended to provide dilation access with or without visualization to the abdominal and thoracic cavities for performing diagnostic and operative abdominal and thoracic procedures.

- Laparoscopic access to the abdominal cavity, both primary and secondary punctures.
- Thoracoscopic access to the thoracic cavity, both primary and secondary punctures.

Device Description/Technological Characteristics:

The Xpan Universal Trocar System provides a universal port solution wherein the 3mm expandable port is radially expandable from 3mm up to 12mm. Xpan is offered in three sizes and is a single use device.

The 5mm and 12mm cannulas are supplied with an optical bladeless tip and include a detachable valve to allow for specimen removal or rapid desufflation. The 3mm expandable trocar can be assembled with the 5mm or 12mm Xpan obturators after tissue insertion or before tissue insertion if desired. The exterior shaft of the 3mm expandable trocar is ribbed to provide security in tissue once inserted in tissue.

Device Description
Description
3mm expandable (up to 12mm) trocar with a 3mm obturator
5mm Cannula with a 5mm Obturator with an optical bladeless tip
12mm Cannula and a 12mm Obturator with an optical bladeless tip

Performance Data:

Nonclinical performance data has been conducted for the Xpan Universal Trocar System was conducted to evaluate safety and performance, where appropriate device performance was compared against the predicate, reference, or legally marketed comparator devices.

Biocompatibility

Biocompatibility evaluation of the subject device was conducted in accordance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and 2020 FDA Guidance, *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1"; Evaluation and testing within a risk management process*. The subject device contacts tissue for less than 24 hours, so the following endpoints were considered, and all materials were found to be biocompatible:

Cytotoxicity

Sensitization

Intracutaneous Irritation

Acute Systemic Toxicity

Material Mediated Pyrogenicity

Bench Testing

Design Verification testing was performed with the subject device. The following performance characteristics were evaluated:

Trocar Insertion Force

Trocar Retention Force

Expansion Force

Instrument Insertion/Removal Force

Light Transmission and Tissue Visualization

Insufflation and Desufflation

Maintenance of Pneumoperitoneum

Instrument Compatibility

Sterilization /Shelf Life

Sterilization validation was conducted in accordance with ISO11135, *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices.*

Shelf life testing was performed to evaluate package integrity and device functionality following artificial aging and simulated transit conditioning.

Animal Studies

No animal studies were performed

Clinical Studies

No clinical studies were performed

Comparison with the Predicate Device:

Substantial equivalence of the Xpan Universal Trocar System is based on comparing the intended use and indications for use and technological characteristics of the predicate device. The following table compares the intended use/indications and key technological characteristics between the Xpan Universal Trocar System and the predicate device. Where technological characteristics are different, reference devices have been identified. These differences are minor and do not raise new questions of safety and effectiveness.

Feature	Subject Device	Predicate device	Reference Device #1	Reference Devices #2 and #3	Comparison
	Xpan Universal Trocar System	VersaStep (K012539)	GeniCon NanoPort 3mm Trocar (K982472)	VersaOne 5mm and 12mm Bladeless Optical Trocars (K112349 and K130435 respectively).	
FDA Classification	Class II	Class II	Class I	Class II	Same
Product Code(s)	GCJ	GCJ	GEA (reclassified 2001)	GCJ	Same as the predicate device
Regulation Number	876.1500	876.1500	878.4800	876.1500	Same as the predicate device
Anatomical Location	Abdominal and Thoracic	Abdominal and Thoracic	Abdominal and Thoracic	Abdominal and Thoracic	Same

Feature	Subject Device	Predicate device	Reference Device #1	Reference Devices #2 and #3	Comparison
	Xpan Universal Trocar System	VersaStep (K012539)	GeniCon NanoPort 3mm Trocar (K982472)	VersaOne 5mm and 12mm Bladeless Optical Trocars (K112349 and K130435 respectively).	
Insertion	Through an incision	Through an incision	Through an incision	Through an incision	Same
Tissue anchoring	Dilation and ridges of expandable members	The dilation of the mesh sheath	Bumps on cannula	Ridges on cannula	Differences do not raise questions of safety and effectiveness
Initial Entry Device (Sheath) Outer Diameter	6.6 mm	4 mm	8.4mm	5mm device: 8.25 mm 12mm device: 15.4 mm	Difference does not raise questions of safety and effectiveness
Expandable Range	5mm and 12mm	5mm and 12mm	N/A	N/A	Same
Method of expansion	Three rigid members form a 3mm cannula and are surrounded by an elastomeric cover. The rigid members and elastomeric cover move radially outwards and expand upon insertion of 5mm or 12mm cannula and obturator	A collapsed mesh constrained by an outer sheath is expanded upon insertion of 5mm or 12mm cannula and blunt obturator through its lumen which disrupts the outer sheath to allow the mesh to expand.	N/A	N/A	Same, both devices accomplish expansion by increasing the radial diameter through a flexible mechanism. Structural differences do not raise new questions of safety and effectiveness

Feature	Subject Device	Predicate device	Reference Device #1	Reference Devices #2 and #3	Comparison
	Xpan Universal Trocar System	VersaStep (K012539)	GeniCon NanoPort 3mm Trocar (K982472)	VersaOne 5mm and 12mm Bladeless Optical Trocars (K112349 and K130435 respectively).	
3mm Trocar/Cannula capability	The Xpan 3mm Expandable Trocar (equivalent of the predicate's sheath) has long, rigid members that form a rigid pathway and lumen for 3mm interventional endoscopic instruments to be used. Can be used standalone 3mm conventional trocar	The sheath is made of flexible material and has no one-way valve, it only creates an initial pathway in the tissue and cannot be used as standalone trocar/cannula for 3mm instruments.	The trocar comprises a cannula that allows entry of 3mm instruments. It also comprises a one-way valve and backup valve that provide sealing	N/A	The capability of the Xpan device as a 3mm trocar does not raise new questions of safety and effectiveness
One Way Valve	Yes In 3mm, 5mm, and 12mm	Yes In 5mm, and 12mm only	Yes	Yes	The capability of the Xpan device at 3mm does not raise new questions of safety and effectiveness
Backup valve for instruments seal	Yes In 3mm, 5mm, and 12mm	Yes In 5mm, and 12mm only	Yes	Yes	The capability of the Xpan device at 3mm does not raise new questions of safety and effectiveness
Range of instrument sizes	Can be used with 3mm instruments in 3mm Expandable	No instruments before expansion of the sheath	3mm instruments	5mm instruments in the 5mm device	The capability of the Xpan device at 3mm does not raise new

Feature	Subject Device	Predicate device	Reference Device #1	Reference Devices #2 and #3	Comparison
	Xpan Universal Trocar System	VersaStep (K012539)	GeniCon NanoPort 3mm Trocar (K982472)	VersaOne 5mm and 12mm Bladeless Optical Trocars (K112349 and K130435 respectively).	
	Device prior to expansion 5mm instruments in 5mm Expanded Device 5mm-12mm instruments in 12mm Expanded Device	5mm instruments in the 5mm Expanded Device 5mm-12mm instruments in the 12mm Expanded Device		5mm-12mm instruments in the 12mm device	questions of safety and effectiveness
Veress Needle Required for insertion	Not required	Required	Not required	Not required	The integrated bladeless 3mm obturator tip in the Xpan device is similar to 3mm reference device and precludes the need for a Veress needle. This difference does not raise new questions of safety and effectiveness
Optical Insertion	Yes For 5mm and 12mm insertions only	No	No	Yes	This difference does not raise new questions of safety and effectiveness
Detachable valve (for Specimen Retrieval)	Yes In 5mm and 12mm	Yes In 12mm only	No	No in the 5mm device Yes in the 12mm device	The additional capability of a detachable valve in both the 5mm and 12mm sizes,

Feature	Subject Device	Predicate device	Reference Device #1	Reference Devices #2 and #3	Comparison
	Xpan Universal Trocar System	VersaStep (K012539)	GeniCon NanoPort 3mm Trocar (K982472)	VersaOne 5mm and 12mm Bladeless Optical Trocars (K112349 and K130435 respectively).	
					does not raise new questions of safety and effectiveness
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	ISO 10993	Same
How Supplied	Sterile, single use	Sterile, single use	Sterile, single use	Sterile, single use	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same

Conclusion:

Substantial equivalence has been demonstrated based upon the supporting data in this submission demonstrating that the Xpan Universal Trocar System is as safe and effective as the legally marketed predicate device (K012539) and does not raise different questions of safety and effectiveness.