November 5, 2021

Unimax Medical Systems Inc.
Monoj Mon Kalita, Ph.D.
Senior Regulatory Affairs Specialist
8F-2, No.127, Ln.235, Pao Chiao Rd.,
Xindian District, New Taipei City
231, Taiwan

Re: K211577
Trade/Device Name: SoftFix Balloon Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 15, 2021
Received: September 20, 2021

Dear Dr. Kalita:

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,

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)*
K211577

Device Name
SoftFixTM Balloon Trocar

Indications for Use *(Describe)*
The SoftFixTM Balloon Trocar have application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments into the body cavity of patients.

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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The following information are provided according to the requirements as per 21 CFR 807.92.

1.1. SPONSOR/APPLICANT INFORMATION

Sponsor/Applicant	Sponsor Contact Information	Date Prepared
Unimax Medical Systems Inc. 8F-2, No.127, Ln.235, Pao Chiao Rd., Xindian Dist., New Taipei City 231,Taiwan	**Monoj Mon Kalita, Ph.D.** Senior Regulatory Affairs Specialist Ph: +886-2-8919-1698 ext. 202 Fax: +886-2-8919-1528 Email: mon@unimaxmeds.com	2021/11/04

1.2. SUBJECT DEVICE INFORMATION

Device Trade Name	:	**SoftFix™ Balloon Trocar**
Classification Name	:	Laparoscope, General & Plastic Surgery
Regulation Number	:	21 CFR 876.1500
Regulatory Class	:	Class II
Product Code	:	GCJ
Regulation Description	:	Endoscope and accessories
Review Panel	:	General & Plastic Surgery
510(k) Number	:	K211577

1.3. PREDICATE DEVICE INFORMATION

Item	Description
Device Name	GelPort® Blunt Tip Trocar System
510(k) Number	K060629
Manufacturer	**Applied Medical Resources Corporation** 22872 Avenida Empresa Rancho Santa Margarita, CA-92688
Item	**Description**
Device Name	Fixation Trocars
510(k) Number	K083638
Manufacturer	**Applied Medical Resources Corporation** 22872 Avenida Empresa Rancho Santa Margarita, CA-92688

1.4. DEVICE DESCRIPTION

The **SoftFix™ Balloon Trocar** is a series of sterile and single-use Trocar intended to be included as an extension to the previously cleared **Unimax Trocar Series**.

In general, the Trocars from **Unimax Trocar Series** consist of an Obturator and a Cannula containing a seal system. The Obturator is used to place the cannula through the incision site into the patient's body cavity where the Cannula remains anchored at a desired position. For that anchoring purpose, previously cleared Trocars belonging to the **Unimax Trocar Series** are equipped with threaded Cannulas or Cannulas with a movable bolster. As a series extension, the Cannulas belonging to the **SoftFix™ Balloon Trocars** are now available with an inflatable balloon and a manually movable bolster to provide stabilization and minimize the fascial trauma during an endoscopic procedure. Whereas these Cannulas are also designed to be compatible with the Obturators belonging to the previously cleared Trocars from the **Unimax Trocar Series.** The balloon and movable bolster combination on the cannula come with two options;

a) "SoftFix™ Balloon – Fixation Ring" combination

b) "SoftFix™ Balloon – Fixation Cone" combination

Similar to Cannulas of the Trocars from the **Unimax Trocar Series,** each Cannula of the **SoftFix™ Balloon Trocars** is a combination of a sleeve and a housing, fitted with a pair of seal and valve to maintain pneumoperitoneum when the Obturator or other laparoscopic devices are inserted or withdrawn through it during the surgical procedures. The Cannula also contains a stopcock with rotation valve at its proximal end in order to allow or prevent passage of any insufflation gas (e.g. CO_2), when needed. Near the stopcock, the Cannula contains an inflation port to inflate/deflate the balloon using a standard syringe. While the movable "fixation ring" can be slid down the Cannula sleeve to adjust its height as well as fixing the Cannula at a desired position, the height of the "fixation cone" can be adjusted by pressing the thumb notch present on it and the Cannula can be anchored at the desired position by affixing fascial sutures on the struts present near the thumb notch.

1.5. PREDICATE COMPARISON

Attribute	GelPort® Blunt Tip Trocar System (Predicate Device)	Fixation Trocars (Predicate Device)	SoftFix™ Balloon Trocar (Subject Device)	Equivalence/ Difference Determination
510(k) Number	K060629	K083638	K211577	**NA**
Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	**Equivalent**
Manufacturer	**Applied Medical Resources Corporation** 22872 Avenida Empresa Rancho Santa Margarita, CA-92688		**Unimax Medical Systems Inc.** 8F-2, No. 127, Lane 235, Pao Chiao Road, Xindian District, New Taipei City, Taiwan	**NA**
Class	II	II	II	**Equivalent**
Product Code	GCJ	GCJ	GCJ	**Equivalent**
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	**Equivalent**
Intended Use	The GelPort Blunt Tip Trocar System is indicated for use in general, abdominal, gynecological and thoracic minimally invasive surgical procedures to establish a	The Fixation Trocar is a sterile, single-use device, intended for use in conjunction with APPLIED's currently marketed trocar products to	The **SoftFix™ Balloon Trocar** have application in a variety of endoscopic procedures to provide a port of entry for endoscopic	**Equivalent**

Attribute	GelPort® Blunt Tip Trocar System (Predicate Device)	Fixation Trocars (Predicate Device)	SoftFix™ Balloon Trocar (Subject Device)	Equivalence/ Difference Determination
	path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic instruments.	establish a path of entry for endoscopic instruments for use during general, abdominal, gynecological and thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments. The Fixation Trocar may be used with an optical tissue separator or a bladed obturator, and with or without visualization for primary and secondary insertions.	instruments into the body cavity of patients.	
Obturators	Optical Obturator	• Optical Obturator • Optical Obturator with insufflation port • Bladed Obturator with safety lock for the shield	• Bladed Obturator with safety lock for the shield • Bladeless Obturator • Optical Obturator • Hasson Obturator	**Different,** Difference in available obturators does not affect the substantial equivalence of the subject device.
Cannula	• Housing with a seal to prevent air-leakage • Housing with safety lock for the obturator • Cannula Sleeve with a stopcock for insufflation	• Housing with a seal to prevent air-leakage • Housing with safety lock for the obturator • Cannula Sleeve with a stopcock for insufflation	• Housing with a seal to prevent air-leakage • Housing with safety lock for the obturator • Cannula Sleeve with a stopcock for insufflation	**Equivalent**
Cannula Fixation Mechanism	• Balloon – Fixation Cone combination on the Cannula	• Balloon – Fixation Ring combination on the Cannula	• Balloon – Fixation Ring combination on the Cannula • Balloon – Fixation Cone combination on the Cannula	**Equivalent**
	Suture Tie on Fixation Cone	-	Suture Tie on Fixation Cone	**Similar** Suture tie is provided only with the 'Fixation Cone' model. This difference is only due to different design aspect and does not alter

Attribute		GelPort® Blunt Tip Trocar System (Predicate Device)	Fixation Trocars (Predicate Device)	SoftFix™ Balloon Trocar (Subject Device)	Equivalence/ Difference Determination
					safety and effectiveness of the Trocar with fixation ring
		Non-latex balloon	Non-latex balloon	Non-latex balloon	**Equivalent**
		Balloon inflation port on the cannula	Balloon inflation port on the cannula	Balloon inflation port on the cannula	**Equivalent**
Cannula Dimension	**Diameter**	5.0 – 12.0 mm	5.0 – 15.0 mm	5.0 – 12.0 mm	**Similar** The Trocars are available in a range of diameters. This variation in diameter is only to allow entry of other endoscopic instruments and does not have any effect on device performance. Additionally, diameter information is printed on the Cannula housing.
	Length	100.0 – 130.0 mm	55.0 – 150.0 mm	70.0 – 100.0 mm	**Similar** Similar to the rational above, the Trocars are available in a range of length. Choice of Trocar length depends on user's preference.
Sterilization		Sterilized using irradiation	Sterilized using irradiation	Sterilized using EtO	**Different,** Difference in sterilization method does not affect the safety and effectiveness of the subject device as it is sterilized by using a validated sterilization method identical to the previously cleared **Unimax Trocar Series**.
Operating Principle		Penetrates the thick tissue layers while providing a port of entry for the endoscopic instruments into	Penetrates the thick tissue layers while providing a port of entry for the	Penetrates the thick tissue layers while providing a port of entry for the	**Equivalent**

Attribute	GelPort® Blunt Tip Trocar System (Predicate Device)	Fixation Trocars (Predicate Device)	SoftFix™ Balloon Trocar (Subject Device)	Equivalence/ Difference Determination
	the body cavity. The balloon fixation mechanism helps to anchor the Cannula at a desired position and reduces its migration.	endoscopic instruments into the body cavity. The fixation mechanism helps to anchor the Cannula at a desired position and reduces its migration.	endoscopic instruments into the body cavity. The fixation mechanism helps to anchor the Cannula at a desired position and reduces its migration.	

1.6. NON-CLINICAL PERFORMANCE TESTING

The following non-clinical testing were conducted to demonstrate that the design and performance requirements were met as well as to determine the substantial equivalence of the subject devices with the predicate devices.

Attribute	Test Method	Acceptance Criteria	Result (PASS/FAIL)
Biocompatibility	In vitro Cytotoxicity test as per ISO 10993-5	Test article shall be non-cytotoxic	PASS
	Irritation test per ISO 10993-10	Test article shall not induce any significant irritation.	PASS
	Skin sensitization test per ISO 10993-10	Test article shall not induce any significant sensitization	PASS
Sterility	Sterilization Validation per ISO 11135	The sterilization method shall be validated	PASS
	Sterile Packaging per ISO 11607-1	The device packaging shall remain sterile during its shelf life period	PASS
Bench Performance Testing	Obturator Insertion Test	Obturators of the devices shall have an insertion force lower than the predefined threshold value when inserted through the cannula.	PASS
	Obturator Removal Test	Obturators of the devices shall have a removal force lower than the predefined threshold value when removed from the cannula.	PASS
	Trocar Penetration Test	The Trocars shall have an insertion force lower than the predefined threshold value when inserted through layers of skin with varying thickness.	PASS
	Cannula Stabilization Test	The Cannulas shall remain stable at its original position after maneuver of instruments with varying sizes.	PASS
	Air-Leakage Test	The Trocars shall not have any leakage and shall be able to maintain a constant value during real use simulation.	PASS
	Balloon Volume Test	The balloons on the Trocars shall be inflated to the recommended volume and shall maintain the predefined threshold diameter.	PASS
	Balloon Rigidity Test	The balloons on the Trocars shall withstand the predefined threshold value when mechanically pulled with a constant force.	PASS
	Fixation Device Retention Test	The fixation device shall withstand the predefined threshold value when mechanically pushed with a constant force.	PASS

1.7. CONCLUSION

The **SoftFix™ Balloon Trocar** has identical intended use with predicate devices as they act as port of entry for the endoscopic instruments into the patient body cavity. In addition to this, the devices incorporate similar Obturators into the Cannulas.

In conclusion, the abovementioned regulatory, technical as well as non-clinical testing summaries demonstrate that the **SoftFix™ Balloon Trocar** is as safe, as effective and perform as equivalent to the predicate devices and hence are found to be substantially equivalent.