October 20, 2023

MediConcepts Technology (Shenzhen) Company Limited
Benjamin Chan
Managing Director
Building No. 37, Tongfu Industrial Estate, Dapeng New
District Shenzhen City, Guangdong Province, China
Shenzhen, Guangdong 518120
China

Re: K232042

Trade/Device Name: NexPort™ Trocar System (TS211001); NexPort™ Trocar System (TS211002); NexPort™ Trocar System (TS211003); NexPort™ Trocar System (TS211010); NexPort™ Trocar System (TS211011); NexPort™ Trocar System (TS211012); NexPort™ Trocar System (TS221001); NexPort™ Trocar System (TS221002); NexPort™ Trocar System (TS221003); NexPort™ Trocar System (TS221010); NexPort™ Trocar System (TS221011); NexPort™ Trocar System (TS221012); NexPort™ Trocar System (TS221020); NexPort™ Trocar System (TS221021); NexPort™ Trocar System (TS221022); NexPort™ Trocar System (TS241020); NexPort™ Trocar System (TS241021); NexPort™ Trocar System (TS241022); NexPort™ Trocar System (TS331001); NexPort™ Trocar System (TS331002); NexPort™ Trocar System (TS331003); NexPort™ Trocar System (TS331004); NexPort™ Trocar System (TS332001); NexPort™ Trocar System (TS332002); NexPort™ Trocar System (TS332003); NexPort™ Trocar System (TS332004); NexPort™ Trocar System (TS332005); NexPort™ Trocar System (TS332006)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 17, 2023
Received: July 10, 2023

Dear Benjamin Chan:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.10.20 14:20:41 -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.

Submission Number *(if known)*

K232042

Device Name

NexPort™ Trocar System (TS211001);
NexPort™ Trocar System (TS211002);
NexPort™ Trocar System (TS211003);
NexPort™ Trocar System (TS211010);
NexPort™ Trocar System (TS211011);
NexPort™ Trocar System (TS211012);
NexPort™ Trocar System (TS221001);
NexPort™ Trocar System (TS221002);
NexPort™ Trocar System (TS221003);
NexPort™ Trocar System (TS221010);
NexPort™ Trocar System (TS221011);
NexPort™ Trocar System (TS221012);
NexPort™ Trocar System (TS221020);
NexPort™ Trocar System (TS221021);
NexPort™ Trocar System (TS221022);
NexPort™ Trocar System (TS241020);
NexPort™ Trocar System (TS241021);
NexPort™ Trocar System (TS241022);
NexPort™ Trocar System (TS331001);
NexPort™ Trocar System (TS331002);
NexPort™ Trocar System (TS331003);
NexPort™ Trocar System (TS331004);
NexPort™ Trocar System (TS332001);
NexPort™ Trocar System (TS332002);
NexPort™ Trocar System (TS332003);
NexPort™ Trocar System (TS332004);
NexPort™ Trocar System (TS332005);
NexPort™ Trocar System (TS332006)

Indications for Use *(Describe)*

This device is a sterile, single-use device and indicated for use in general, thoracic, gynecologic, or minimally invasive procedures to establish a path of entry for minimally invasive instruments.

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

NexPort™ Trocar System

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Date: July 8, 2023

2. Submitter: MediConcepts Technology (Shenzhen) Company Limited

Building No. 37, Tongfu Industrial Estate, Dapeng New District, Shenzhen City, Guangdong Province, 518120, P.R. China

Contact person: Nick Xu
Regulatory Affairs
MediConcepts Technology (Shenzhen) Company Limited

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Telephone: +86 13338102750
Email: nick.xu@mediconcepts.com.hk

3. Device Name: NexPort™ Trocar System

Product Code	Classification	Regulation Section	Panel
GCJ	Class II	21 CFR Part 876.1500 Laparoscope, General & Plastic Surgery	Endoscope & accessories

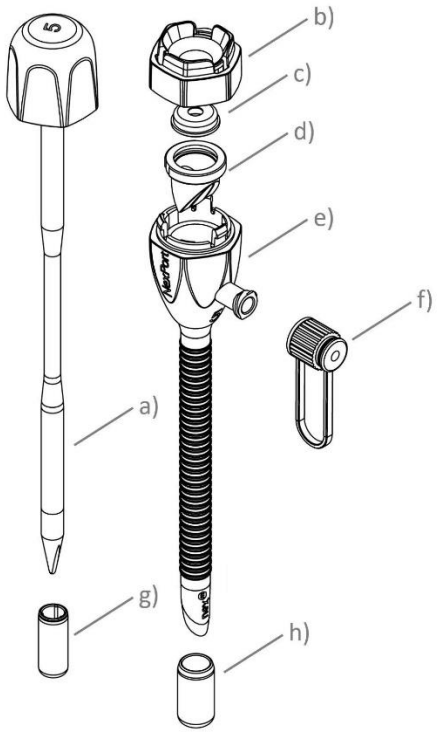
4. Predicate Devices:

Predicate Device 510 (k) number	Predicate Device name
K201641	Disposable Laparoscope Trocar
K180208	Disposable Endoscopic Trocar

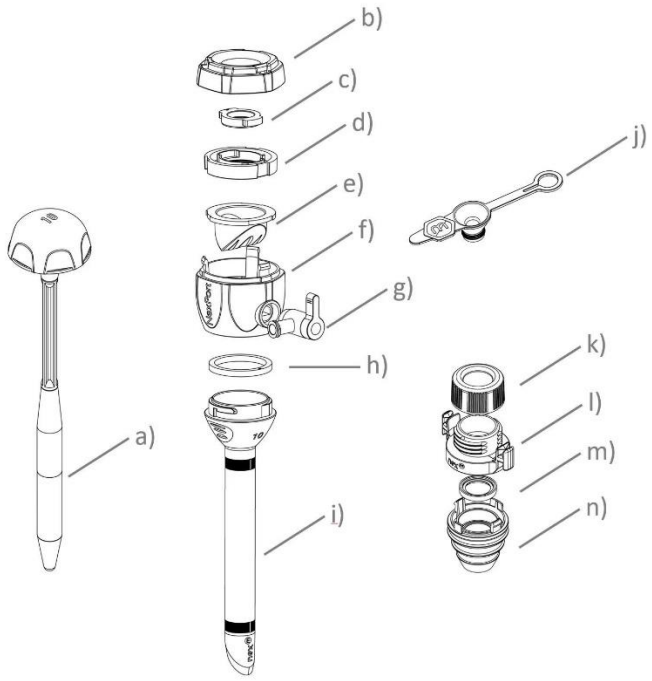
5. Device Description:

The NexPort™ Trocar System is a basic equipment used during laparoscopic surgical, and the surgical device will enter into abdominal cavity via the passage established by the trocar. The proposed devices are available to accommodate 5mm and 10mm surgical instruments.

The 5mm NexPort™ Trocar System is consisted of:



a) Obturator Shaft
b) Cannula Cap
c) Seal
d) Duckbill Valve
e) Cannula Body
f) Luerlock Cap
g) Obturator Tip Protector
h) Cannula Tip Protector



The 10mm NexPort™ Trocar System is consisted of:

a) Obturator Shaft
b) Cannula Cap
c) Seal
d) Cannula Intermediate Plate
e) Duckbill Valve
f) Cannula Housing
g) Stopcock
h) Face Seal
i) Cannula Sleeve
j) Reducer
k) Adaptor Cap
l) Adaptor Top Body
m) Adaptor Seal
n) Adaptor Bottom Body

Table 5.1 the differences between these models

Diameter	5mm	10mm
Length	65mm 70mm 95mm	105mm

Cannula Type	Microgroove Cannula Ribbed Cannula	Microgroove Cannula
Pack	Single Pack Dual Pack	Single Pack
Obturator	MicroFlat Obturator	MicroFlat Obturator Blunt Obturator Dilating Obturator
Transparency	Transparency Non-transparency	Transparency Non-transparency
Adaptor	N/A	Standard Adaptor Slimline Adaptor

6. Intended Use/Indications for Use:

The NexPort Trocar System is a sterile, single-use device and indicated for use in general, thoracic, gynecologic, or other minimally invasive procedures to establish a path of entry for minimally invasive instruments.

7. Technology:

The NexPort Trocar System employs the same fundamental scientific technology as its predicate devices.

8. Determination of Substantial Equivalence:

Comparison to Predicate Devices:

Below table is the summary comparison of features of the NexPort™ Trocar System and the predicate devices.

Table 5.2 Features comparison between proposed device and predicate devices

Feature	**Proposed Device: NexPort™ Trocar System**	**Predicate Device: Disposable Laparoscope Trocar (K201641)**	**Predicate Device: Disposable Endoscopic Trocar (K180208)**	**Discussion of Differences**
Product Code	GCJ	GCJ	GCJ	Identical
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Identical
Classification	Class II	Class II	Class II	Identical

Feature	Proposed Device: NexPort™ Trocar System	Predicate Device: Disposable Laparoscope Trocar (K201641)	Predicate Device: Disposable Endoscopic Trocar (K180208)	Discussion of Differences
Intended/ Indications for use	NexPort™ Trocar System is a sterile, single-use device and indicated for use in general, thoracic, gynecologic, or minimally invasive procedures to establish a path of entry for minimally invasive instruments.	The Disposable Laparoscope Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.	The Disposable Endoscopic Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.	Identical
Application Sites	Abdominal Thoracic Gynecologic	Abdominal Thoracic Gynecologic	Abdominal Thoracic Gynecologic	Identical
Principles of Operation	1. Installation Surgeon inserts the obturator in the cannula. 2. Insertion Surgeon makes an incision on the patients' abdominal wall and inserts the installed laparoscopic trocar system via the incision. 3. Operation Surgeon removes the obturator from the cannula. Surgeon can insert the corresponding diameter instrument in the cannula based on his/ her needs.	Unkonwn	During the operation, the trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for endoscopic instruments.	Identical
Signle use	Yes	Yes	Yes	Identical
Operation Mode	Manually	Manually	Manually	Identical
Diameter	5mm, 10mm	5mm, 10mm, 12mm, 15mm	5mm, 10mm, 12mm	The diameters of proposed device are contained in the predicated device (K201641).
Length	65mm, 70mm, 95mm, 105mm	96mm, 98mm, 99mm, 111mm	100mm	Different, the devices are all offered in a variety of lengths to accommodate various clinical use.

Feature	Proposed Device: NexPort™ Trocar System	Predicate Device: Disposable Laparoscope Trocar (K201641)	Predicate Device: Disposable Endoscopic Trocar (K180208)	Discussion of Differences
Biocompatibility	Cytotoxicity Sensitization Intracutaneous reactivity Acute systemic toxicity Material-mediated pyrogenicity	Cytotoxicity Sensitization Intracutaneous reactivity Acute systemic toxicity Material-mediated pyrogenicity	Cytotoxicity Sensitization Intracutaneous reactivity Acute systemic toxicity Material-mediated pyrogenicity	Identical
SAL	$<=10^{-6}$	$<=10^{-6}$	$<=10^{-6}$	Identical
Method of Sterilization	Irradiation	Ethylene Oxide sterilization	Irradiation	The proposed device adopts the same method of sterilization as its predicated device Disposable Endoscopic Trocar (K180208)

From the comparison summary table, the NexPort™ Trocar System is substantially equivalent to the predicated devices with regard to intended use, technological characteristics, safety and effectiveness.

- The devices are all intended for used in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.
- The devices are all offered in a variety of lengths and Diameter to accommodate various anatomical locations and differences in patient anatomy.
- The proposed device and its predicated device Disposable Endoscopic Trocar (K180208) have the same Principles of Operation.
- The devices are all offered with single use, the Sterilization Assurance Level (SAL) are all $<= 10^{-6}$, and proposed device adopts the same method of sterilization as its predicated device Disposable Endoscopic Trocar (K180208).

9. Summary of Non-Clinical Tests:

NexPort Trocar System has been evaluated for biocompatibility, accelerated aging test and real-time aging test as well as shelf life, sterilization, and mechanical safety, meantime in vivo study was conducted on porcine model to evaluate the penetration force, fixation force and tip integrity have been found to conform to applicable medical device safety standards. The NexPort Trocar System complies with below voluntary standards:

ANSI AAMI ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

ANSI AAMI ISO 10993-5: 2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ANSI AAMI ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation.

ANSI AAMI ISO 11137-1: 2006/(R)2015 Sterilization of health care products - Radiation - Part 1: Requirements for development.

ANSI AAMI ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.

ANSI AAMI ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

ANSI AAMI ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

ASTM F1140/F1140M-13: 2020(E1) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.

ASTM F88/F88M:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials.

ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

ASTM F1980-16 Sterile hypodermic needles for single use - Requirements and test methods.

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Performance testing (Verification)
- Safety testing (Verification)

The NexPort Trocar System is provided with sterilization and is biocompatible.

10. Conclusion

MediConcepts Group considers the NexPort Trocar System to be as safe, as effective, and performance is substantially equivalent to the predicate devices.