June 21, 2021

New View Surgical, Inc.
℅ Maureen O'Connell
President
O'Connell Regulatory Consultant, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K211250
Trade/Device Name: VisionPort System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, HET
Dated: April 23, 2021
Received: April 26, 2021

Dear Maureen O'Connell:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211250

Device Name
VisionPort™ System

Indications for Use *(Describe)*

The VisionPort System is intended to be used in diagnostic and therapeutic procedures for endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs to establish a path of entry for endoscopic instruments and to provide an image of the surgical field. The trocar may be used with or without visualization for primary and secondary insertions.

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.

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510(k) SUMMARY

(K211250)

New View Surgical, Inc.
VisionPort System

SUBMITTER
New View Surgical, Inc.
555 Massachusetts Ave. Ste. 5
Boston, MA 02118

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: June 2, 2021

DEVICE
Trade Name of Device: VisionPort System
Common or Usual Name: Laparoscope
Classification Name(s): Laparoscope, General & Plastic Surgery; 21 C.F.R. §876.1500 and Laparoscope, Gynecologic (and Accessories); 21 C.F.R. §884.1720
Regulatory Class: II
Product Code(s): GCJ and HET

PREDICATE DEVICE(S)
Primary: Xenocor Xenoscope Laparoscopic System cleared in K161838
Secondary: ENDOPATH XCEL Bladeless Trocar cleared in K122511

DEVICE DESCRIPTION
The VisionPort System consists of an access port with an integrated camera and light source, the handpiece, a wired control pad to control the camera functions, and a control unit, specifically:

1. VisionPort System Handpiece – single use
    a. HD camera and lighting module
    b. 12.9mm internal diameter access port with 5-12mm instrument seal
    c. Lens cleaning system (saline wash and wiper blade)
    d. Connections for saline wash source and insufflation tubing
    e. Removable obturator designed for visible entry

2. VisionPort System Control Pad – single use
    a. Camera control functions (zoom, pan)

b. Light emitting diode (LED) adjustment
c. Image capture and display control buttons

3. VisionPort System Control Unit
   a. System power
   b. Image processing (no patient data recording or retention)
   c. Outputs to operating room monitor(s) and/or third-party Data Control Unit (for image capture and printing options)

INDICATIONS FOR USE

The VisionPort System is intended to be used in diagnostic and therapeutic procedures for endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs to establish a path of entry for endoscopic instruments and to provide an image of the surgical field. The trocar may be used with or without visualization for primary and secondary insertions.

SUBSTANTIAL EQUIVALENCE

The VisionPort System described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device. The VisionPort System is substantially equivalent to the Xenocor Xenoscope Laparoscopic System cleared in K161838 and a secondary predicate device, the ENDOPATH XCEL Bladeless Trocar cleared in K122511. A comparison to the primary predicate device is provided in Table 1 and to the secondary predicate device in Table 2. The combined intended use of the primary predicate and secondary predicate is the same as the intended use of the VisionPort System.

Table 1
VisionPort System Substantial Equivalence: Primary Predicate Device

Characteristic	**VisionPort System**	**Xenocor Xenoscope Laparoscopic System**
510(k) Number	K211250	K161838/K171344
Product Code	GCJ, HET	GCJ, HET
Indications for Use	Intended to be used in diagnostic and therapeutic procedures for endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs to establish a path of entry for endoscopic instruments and to provide an image of the surgical field. The trocar may be used with or without visualization for primary and secondary insertions.	Intended to be used in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs.
Clearance Type	Prescription	Prescription
User	Healthcare Professional	Healthcare Professional
Where Used	Hospital, Surgery Center	Hospital, Surgery Center

System Description	The system includes the following components: -VisionPort System Handpiece -VisionPort System Control Pad -VisionPort System Control Unit	The system includes the following components: -Xenoscope Laparoscope Device -Xenoscope Dongle
Component Comparison	VisionPort System Handpiece	Xenoscope Laparoscope
Image Sensor	CMOS	CMOS
Lens	0^{o}	0^{o}
LEDs	2	1
Video Image	High-definition video	High-definition video
Image Transfer	Video cable from camera/scope to Control Unit	Video cable from camera/scope to Control Unit (Dongle)
Placement into Body Cavity	Incorporates an access port/trocar	Inserted through an access port/trocar
Lens Cleaning	Incorporates a lens cleaning system (saline flush and wiper)	No lens cleaning system
Camera Focus	Fixed Focus	Manual Focus
Camera Zoom	Electronic Zoom	Manual Zoom
Camera Light	Light (LED) Attenuation	Light (LED) Attenuation
Camera Monitor	Monitor Display Control	Monitor Display Control
Camera Image Capture Relay	Image Capture Relay using third party image capture system	NA
Sterility	Single use sterile	Single use sterile
Component Comparison	VisionPort System Control Unit	Xenoscope Dongle
Use	Multi-use	Multi-use
Image Transfer from Camera/Scope to Control Unit	Video Cable	Micro-HDMI
Image Transfer from Control Unit to Monitor	DVI	HDMI v1.3
USB	2.0 service port (manufacturing)	3.0 service port (manufacturing)
Standards Compliance		
Electrical Safety	Per IEC 60601-1	Per IEC 60601-1
EMC	Per IEC 60601-1-2	Per IEC 60601-1-2
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1

Table 2
VisionPort System Substantial Equivalence: Secondary Predicate Device

Characteristic	**VisionPort System**	**ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology**
510(k) Number	K211250	K122511

Product Code	GCJ, HET	GCJ
Indications for Use	Intended to be used in diagnostic and therapeutic procedures for endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs to establish a path of entry for endoscopic instruments and to provide an image of the surgical field. The trocar may be used with or without visualization for primary and secondary insertions.	Has applications in abdominal, thoracic, and gynecological 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.
Clearance Type	Prescription	Prescription
User	Healthcare Professional	Healthcare Professional
Where Used	Hospital, Surgery Center	Hospital, Surgery Center
Components	Sleeve and obturator	Sleeve and obturator
Cannula Length	100 mm	100 mm
Cannula Inner Diameter	12.9 mm	12.9 mm
Cannula Outer Diameter	17.8 mm	15.5 mm
Endoscopic View	Incorporates a 0-degree endoscopic view of the trocar tip and provides visibility of individual tissue layers during insertion using an image capture chip, light source and mirror	Accommodates a 0-degree or 30-degree endoscope to view the trocar tip and provides visibility of individual tissue layers during insertion.
Seal System	The sleeve has a two-seal system for maintaining pneumoperitoneum. The trocar sleeves contain two seals, an outer integrated non-removable self-adjusting seal that accommodates instruments ranging from 5 to 12 mm in diameter and an internal seal.	The sleeve has an integrated two-seal system for maintaining pneumoperitoneum. The trocar sleeves contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 to 12 mm in diameter and an internal seal.
Stopcocks	The sleeve has two welded stopcocks on the side of the cannula assembly, both compatible with standard luer lock fittings which provide for attachment of insufflation tubing and a saline flush for lens cleaning.	The sleeve has one welded stopcock assembly, which is compatible with a standard luer lock fitting which provides for attachment of insufflation tubing.
Stability Threads	Sleeve cannula contains integrated stability threads for abdominal wall retention.	Sleeve cannula contains integrated stability threads for abdominal wall retention.

The VisionPort System has the same technological characteristics as the combination of the primary and secondary predicate devices. The different technological characteristics of the

devices do not raise different questions of safety and effectiveness. Performance data is provided which supports substantial equivalence.

PERFORMANCE DATA
Non-clinical testing was performed to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

Sterilization and Shelf Life
Sterilization validation was performed as described in ISO 11135:2014, Sterilization of health-care products -Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. The sterilization assurance level (SAL) is 10^{-6}.

Testing of EtO residuals was conducted per ISO 10993-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. VisionPort System Handpiece samples met the requirements of the standard.

Testing of package seal strength was performed in accordance with ASTM F88 - Standard Test Method for Seal Strength of Flexible Barrier Materials. All samples demonstrated a seal strength greater than 1.0 lbf/in specification. Visual inspection shows that all seals met specifications with no anomalies noted. The shelf life is confirmed by age testing both accelerated and real time in accordance with ASTM 1980-02, Reference Standard Guide for Accelerated Aging of Sterile Medical Device Packages.

Biocompatibility Testing
The materials used for the VisionPort System comply with biocompatibility requirements outlined in ISO 10993-1:2009 and the Guidance for Industry and Food and Drug Administration Staff, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process* and are considered to be biocompatible. The contact type of the VisionPort System is: external communicating, tissue contact with limited contact duration and testing was provided to show compliance with ISO 10993-1. The battery of tests included:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Systemic Toxicity
- Pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)
The VisionPort System was tested for electrical safety and found to be in compliance with IEC 60601-1, IEC 60601-1-6, IEC 62366-1 and IEC 60601-2-18, and for electromagnetic compatibility to IEC 60601-1-2.

Functional Testing
Testing was performed to verify that the VisionPort Handpiece functions as intended:

- When tested in accordance with ISO 8600-1 through ISO 8600-6. All test results met acceptance criteria and were performed in accordance ISO 8600.
- In accordance with design input requirements. The test data demonstrates that the VisionPort System functions as intended and in accordance with design input requirements.

Testing was provided which compared performance of the VisionPort System compared to the secondary predicate device (ENDOPATH® XCEL® Bladeless Trocar with OPTIVIEW Technology (K122511)) and to document substantial equivalence in performance related to recommended use. The testing showed that the VisionPort System can be operated in simulated use conditions when used in accordance with the Manual and IFU and is equivalent to the predicate systems for the attributes tested in this protocol.

CONCLUSIONS

The performance data supports the safety of the device and shows that the device performs as intended. The substantial equivalence discussion supports the finding of substantial equivalence to the predicate devices.