510(k) K132203

SECTION 1. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for PneuVIEW® XE VeryClear™ Gas Evacuation Cannula.

SUBMITTER'S NAME:	LEXION Medical LLC
ADDRESS:	545 Atwater Cr. St. Paul, MN 55103
CONTACT PERSON:	Bernard (Bud) Horwath Consultant to LEXION Medical
ADDRESS:	4486 Timberline CT Vadnais Heights, MN 55127
TELEPHONE NUMBER:	651-231-1761
FAX NUMBER:	651-636-1671
DATE OF SUBMISSION:	12 July 2013

SEP 2 0 2013

1. **Identification of device**
   Proprietary Name: PneuVIEW® XE VeryClear™ Gas Evacuation Cannula
   Common Name: Path of entry access port device and smoke evacuation system
   Classification Status: Class II per regulations 876.1500, Product Code: GCJ
   Class I per regulation 876.1500, Product Code: FCZ

2. **Equivalent devices**
   LEXION Medical believes that PneuVIEW® XE VeryClear™ Gas Evacuation Cannula is substantially equivalent to the following devices:

   SurgiQuest Trocar with Integrated Insufflator, 510(k) K103692
   Pneu*VIEW*®*XE* Smoke Evacuation System, 510(k) exempt
   Insu*flow*® Synergy™ Port, 510(k) K120640

   PneuVIEW® XE VeryClear™ Gas Evacuation Cannula is an accessory device with an integral path of entry access port device with smoke evacuation mechanism similar to the predicate devices. The PneuVIEW® XE VeryClear™ has the same intended use as the predicate devices.

3. **Description of the Device**
   The PneuVIEW® XE VeryClear™ Gas Evacuation Cannula (Dual and Single Lumen Port) is an integral path of entry access port device with smoke evacuation mechanism intended for use in the surgical cavity during minimally invasive surgery. The PneuVIEW® XE VeryClear™ is a disposable single use device consisting of a path of entry access port

device with filter and tubing with a multi-position stopcock valve. The PneuVIEW® XE VeryClear™ can be connected to a vacuum source for smoke evacuation.

The integral path of entry access port device is designed and constructed similarly to the predicate Insu*flow*® Synergy™ Port access device with a sealed instrument access lumen. Just as the Insu*flow*® Synergy™ Port, the PneuVIEW® XE VeryClear™ has a dual-lumen or single-lumen path of entry access device 5 mm configuration for surgical instrument manipulation and smoke evacuation.

4. **Intended use**
PneuVIEW® XE VeryClear™ Gas Evacuation Cannula has applications in thoracic, abdominal and gynecologic minimally invasive endoscopic surgical procedures to establish a path of entry for endoscopic instruments and to evacuate smoke and plume generated during minimally invasive surgery from the surgical cavity to aid visualization.

5. **Technological characteristics, comparison to predicate device.**
Technically, the PneuVIEW® XE VeryClear™ path of entry access port device is essentially equivalent to the Insu*flow*® Synergy™ Port access device predicate with minor design configuration and material colorant differences. The smoke evacuation system is also essentially the same as the PneuVIEW® XE Smoke Evacuation System, with tubing and valves that are connected to a vacuum source for smoke removal. In addition, the SurgiQuest Trocar with Integrated Insufflator is also a combination of devices featuring an access port and smoke evacuation capabilities, just as the PneuVIEW® XE VeryClear™. The indications for use for the PneuVIEW® XE VeryClear™ are patterned after and essentially the same as the predicate devices.

6. **Discussion of performance testing.**
Extensive performance testing has been conducted to assure that the PneuVIEW® XE VeryClear™ performs in accordance with its specifications and applicable standards. Flow/pressure performance and seal leak integrity testing were successfully completed. Since the access port device is the same size and configuration as the Insu*flow*® Synergy™ Port 5 mm device, the insertion/removal testing previously submitted is directly applicable. In addition, biocompatibility per ISO 10993-1 was demonstrated.

7. **Conclusion**
Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that PneuVIEW® XE VeryClear™ Gas Evacuation Cannula (Dual and Single Lumen Port) is substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 20, 2013

Lexion Medical, LLC
% Mr. Bernanrd Horwath
Regulatory Consultant
4486 Timberline Court
Vadnais Heights, Minnesota 55127

Re: K132203
Trade/Device Name: PneuVEIW® XE VeryClear™ Gas Evacuation Cannula (Dual and Single Lumen Ports)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, HIF
Dated: July 12, 2013
Received: July 23, 2013

Dear Mr. Horwath:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K132203

Device Name: PneuVIEW® XE VeryClear™ Gas Evacuation Cannula (Dual and Single Lumen Ports)

Indications for Use:

PneuVIEW® XE VeryClear™ Gas Evacuation Cannula has applications in thoracic, abdominal and gynecologic minimally invasive endoscopic surgical procedures to establish a path of entry for endoscopic instruments and to evacuate smoke and plume generated during minimally invasive surgery from the surgical cavity to aid visualization.

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.09.20 10:41:14 -04'00'

(Division Sign-off) for MXM
Division of Surgical Devices
510(k) Number: K132203