SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 2 2013

1. GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Yves Arboy, President, VECTEC
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03270 Hauterive FRANCE
Establishment Registration No.: 3005459904

1.2 Official Correspondent

Diane Horwitz, Ph.D., RAC
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1.3 Date of Preparation

August 2, 2013

2. NAME OF THE DEVICES

2.1 Trade/Proprietary Names

VECTEC Disposable Pneumoperitoneum Needle

2.2 Classification Information

Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR 876.1500
Class:	II
Common Name:	Pneumoperitoneum Needle
Product Codes:	FHO, FHP, HIF
Panel:	Gastroenterology/Urology

3. DESCRIPTION OF THE DEVICE

The VECTEC Disposable Pneumoperitoneum Needle is a disposable, single-use, sterile surgical tool used in laparoscopy for insufflation of the abdominal cavity prior to use of a trocar during abdominal surgery. The device is sterilized using a traditional, validated ethylene oxide procedure per ISO 11135-1: 2007 to a SAL of 10^{-6} and with acceptable residual EO levels per ISO 10993-7: 2008.

4. INTENDED USE / INDICATIONS FOR USE

The VECTEC Disposable Pneumoperitoneum Needle is a single-use, sterile device intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish a pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

5. PREDICATE DEVICES

	Predicate 1	Predicate 2
Device Name:	Pneumo-Matic Insufflation Needle	Endopath Veress Needle
510(k) Number:	K970788	K910855
Manufacturer:	Apple Medical Corporation	Ethicon Endosurgery Inc.

6. COMPARISON TO PREDICATES

This 510(k) submission claims substantial equivalence to the predicate devices by Apple Medical Corp., Pneumo-Matic Insufflation Needle, FHO/ 876.1500, K970788 and Ethicon Endosurgery Inc., Endopath Veress Needle, FDP/ 876.1500, K910875. The table below provides an overview of the comparison of the new device to the predicate devices. Overall, although there are minor differences between the design and materials between the devices, substantial equivalence between the new device and the predicate devices has been demonstrated.

Characteristic	List of Similar Characteristics: VECTEC Pneumoperitoneum Needle vs. Predicate Devices
Users	Surgeons in operating room
Intended Use/Indication for Use	Access to peritoneal space during laparoscopic surgery for insufflation with CO_2
Single-use disposable	Yes
Sterilized	Yes
Length	120 mm and 150 mm
Diameter	2.1 mm (14G)
Luer Lock connector	Yes
Spring-loaded	Yes
Indicator for when in peritoneal cavity	Yes (clear hub with red indicator)
On/Off gas flow switch	Present
Compliance with ISO 10993 for biocompatibility	Complies

7. PERFORMANCE TESTING

The VECTEC Disposable Pneumoperitoneum Needle is composed of biocompatible materials. Cytotoxicity, irritation and sensitization testing were conducted according to ISO 10993-1: 2009, ISO 10993-5:2009, ISO 10993-10: 2010, and ISO 10993-12: 2007. Sterilization validation was performed according to ISO 11135-1: 2007 and ethylene oxide residuals were monitored according to ISO 10993-7: 2008.

Mechanical bench testing of Luer lock operation, spring assembly resistance, disassembly test and indicator tests were conducted in comparison with the predicate, Ethicon Endopath Veress Needle. *In vivo* testing including needle puncture tests and gas flow tests of insufflation in a full-sized porcine model were conducted by a general surgeon with experience in laparoscopy. All performance tests show acceptable results and validate that the VECTEC Disposable Pneumoperitoneum Needle meets the intended use and product specifications.

8. CONCLUSIONS

Based on the substantial equivalence analysis, which demonstrates similar intended use and technology between the new device and the predicates, the VECTEC Disposable Pneumoperitoneum Needles are concluded to be as safe and effective and substantially equivalent to the predicate devices, supporting the clearance of the VECTEC Disposable Pneumoperitoneum Needles.

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

August 2, 2013

VECTEC
% Diane Mandell Horwitz, Ph.D., RAC
Regulatory Consultant
Mandell Horwitz Consultants, LLC
2995 Steven Martin Drive
Fairfax, VA 22031

Re: K121370
Trade/Device Name: VECTEC Disposable Pneumoperitoneum Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FHO, FHP, HIF
Dated: July 24, 2013
Received: July 24, 2013

Dear Diane Mandell Horwitz,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K121370

Device Name: VECTEC Disposable Pneumoperitoneum Needle

Indications for Use:

The VECTEC Disposable Pneumoperitoneum Needle is a single-use, sterile device intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish a pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121370