1000346

Virtual Ports
Laparoscopy Systems

Virtual Ports Ltd.

510(K) SUMMARY

MAR 10 2010

510(k) Number K_____

Preparation Date: January 30, 2010

Applicant's Name: Virtual Ports Ltd.
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Trade Name: EndoClear™ System

Common name: Accessory to a Laparoscope

Classification: **Name**: Endoscope and accessories
Product Code: GCJ
Regulation No: 876.1500
Class: II
Classification Panel: General and Plastic Surgery

Predicate Device: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Clearance Date
EndoClear™ System	K080051	21 Mar, 2008

Device Description:

The Virtual Ports EndoClear™ system is an accessory tool for laparoscopic procedures that consists of the EndoClear™ Lens Cleaner and the Virtual Ports Applier. The EndoClear™ Lens Cleaner is an internally anchored, hands-free, laparoscope lens

cleaning device that is attached to the internal operating cavity wall and remains in position until completion of the surgery, enabling the surgeon to effectively clean the laparoscope lens of blood, fat, fog, and secretions without removing it from the cavity. The EndoClear™ Lens Cleaner is introduced via a cannula using the Virtual Ports Applier, which introduces the EndoClear™ Lens Cleaner into the cavity, enables positioning of the device under endoscopic guidance, anchors it to the internal cavity wall, and removes the EndoClear™ Lens Cleaner at the end of the surgical procedure.

Intended Use Statement:

EndoClear™ Laparoscopes Accessory is intended to be used by qualified physicians to provide endoscope lens cleaning for uninterrupted visualization of internal structures in a wide variety of diagnostic and therapeutic laparoscopic procedures.

Technical Characteristics:

Both the modified EndoClear™ System and its predicate device (EndoClear™ System; K080051) are internally anchored, hands-free, laparoscope lens cleaning devices. Both devices are attached to the internal operating cavity and remain in position until completion of the surgery.

Technical Modifications from Predicate Device:

The modifications between the modified EndoClear™ System and its predicate device EndoClear™ System; (K080051) are:

- Engineering changes
- Changes in materials

- The Virtual Ports Applier is reusable
- Labeling change (Introducer to Applier)

Substantial Equivalence:

The modified EndoClear™ System:

- has the same intended use
- incorporates the same technology

As the EndoClear™ System, cleared in K080051.

Performance Validation:

Performance Testing - bench tests

Bench tests were performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

Materials:

Materials of the EndoClear™ System that are in contact with the human body are biocompatible in accordance with ISO 10993-1

Conclusion:

Virtual Ports Ltd. believes that, based on the information provided in this submission, the modified EndoClear™ System is substantially equivalent to its predicate device without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Virtual Ports Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

MAR 10 2010

Re: K100346
Trade/Device Name: EndoClear™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 02, 2010
Received: February 18, 2010

Dear Mr. Levy:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: EndoClear™ System

Indications for Use:

EndoClear™ Laparoscopes Accessory is intended to be used by qualified physicians to provide endoscope lens cleaning for uninterrupted visualization of internal structures in a wide variety of diagnostic and therapeutic laparoscopic procedures.

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

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices

510(k) Number

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100346