FEB - 4 2011

SUMMARY OF SAFETY AND EFFECTIVENESS K103707

1. GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Yves Arboy, President
VECTEC
Bioparc
03270 Hauterive
FRANCE
Establishment Registration: 3005459904

1.2 Date of Preparation

December 17, 2010

2. NAME OF THE DEVICES

2.1 Trade/Proprietary Names

VECTEC Disposable Monopolar Connection Cable

2.2 Classification Information

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR § 878.4400
Class:	II
Product Code:	GEI, electrosurgical, cutting and coagulation and accessories
Panel:	General and Plastic Surgery

3. PREDICATE DEVICE

This 510(k) submission claims substantial equivalence to the following predicate device: Karl Storz Endoscopic High Frequency Monopolar Cord (Karl Storz Endoscopy-America, Inc.), GEI/ 878.4400, K934985.

4. DESCRIPTION OF THE DEVICES

The VECTEC Disposable Monopolar Cable is a 2.5 m cable used during routine laparoscopy and endoscopy procedures as the means of conveying high frequency electrical energy from a standard electrosurgical generator to standard electrosurgical instruments during surgery. Examples of such instruments include the range of VECTEC monopolar Scissors, Forceps, Dissectors, and Hook. VECTEC Disposable Monopolar Cables are single-use, sterile devices that are packaged individually and have a 2 or 5-year shelf life providing that the packaging

is not damaged. The VECTEC monopolar cable is convenient for use in the operating room while having the high degree of performance expected from a surgical monopolar cable.

5. INDICATIONS FOR USE AND INTENDED USE

The VECTEC Disposable Monopolar Connection Cable is a sterile single-use device used to connect high frequency monopolar electrosurgical generators to various models of electrosurgical surgical instruments during laparoscopic and endoscopic surgery.

6. SUBSTANTIAL EQUIVALENCE

This 510(k) submission claims substantial equivalence to the following predicate device: Karl Storz Endoscopic High Frequency Monopolar Cord (Karl Storz Endoscopy-America, Inc.), GEI/ 878.4400, K934985.

A comparison of the intended use statements and the an overview of the technology reveals the similarities between the predicate devices and the VECTEC devices:

7. PERFORMANCE TESTING

The monopolar cable has been tested against all applicable requirements of IEC 60601-2-2:2006, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.

Sterilization is performed using ethylene oxide in accordance with ISO 11135-1:2007, with a SAL of 10^{-6}.

8. CONCLUSIONS

Based on the technical testing and dimensional information and intended use information provided, the VECTEC Disposable Monopolar Cable has been shown to be substantially equivalent to the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

VECTEC
% Mandell Horwitz Consulting, LLC
Dr. Diane Mandell Horwitz
2995 Steven Martin Drive
Fairfax, Virginia 22031

FEB - 4 2011

Re: K103707
Trade/Device Name: VECTEC Disposable Monopolar Connection Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 17, 2010
Received: December 20, 2010

Dear Dr. 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,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K103707

Device Name: VECTEC Disposable Monopolar Connection Cable

Indications for Use:

The VECTEC Disposable Monopolar Connection Cable is a sterile single-use device used to connect high frequency monopolar electrosurgical generators to various models of electrosurgical surgical instruments during laparoscopic and endoscopic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103707

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