Cambridge Endoscopic Devices, Inc.
119 Herbert Street
Framingham, MA 01702

K061425

510K Summary of Safety and Effectiveness
May 17, 2006

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1. **Sponsor Name**
Cambridge Endoscopic Devices, Inc.

2. **Device Name**
Proprietary Name: pureWrist™ electrocautery laparoscopic instruments
Common/Usual Name: Electrosurgical cutting and coagulation device and accessories

3. **Identification of Predicate or Legally Marketed Device**
The Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® Endoscopic Instruments cleared and under K984240.

4. **Device Description**
The pureWrist™ electrocautery laparoscopic instruments are sterile, single use disposable instruments for use through appropriately sized surgical trocars. The instruments consist of a rotating insulated shaft with a 5mm diameter. The distal end of the shaft has the respective end effector attached (scissors, dissector, or hook). The proximal end of the shaft is attached to an ergonomically shaped handle with a rotating knob that allows the shaft to rotate 360 degrees in either direction. The handle contains the actuation mechanism for the respective end effector. The lever on the handle is compressed and released to activate the instrument jaws or scissor blades. Each instrument has a monopolor cautery connector that extends from the bottom of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and proper generator.

5. **Intended Use**
The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

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6. Comparison of Technological Characteristics

The pureWrist™ electrocautery laparoscopic instruments have the same technological characteristics as the predicate devices. Each of the devices are scissors, graspers, or dissectors that coagulate tissue using monopolar technology. Each use sharp objects to permit the surgeon to cut or dissect tissue. Each of the devices are connected to the same or similar electrosurgical generators and use similar power ranges for operation. The devices have the same intended use, indications for use, technological features including similar design, performance, and material characteristics which further supports the concept of substantial equivalence.

7. Performance Testing

Pre-clinical testing was used to evaluate performance to ensure that the device can be used as designed. The testing evaluated ergonomics of the handle and rotating knob, tissue trauma, grasping and dissecting ability, and electrical insulation requirements. The studies demonstrated acceptable reliability and design performance relative to the predicate device.

8. Statement of Equivalency

Based on the design and intended use, the Cambridge Endoscopic Devices, Inc. pureWrist™ electrocautery laparoscopic instruments are substantially equivalent to the Ethicon Endo-Surgery, Inc. ENDOPATH® instruments cleared under K984240.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2006

Cambridge Endoscopic Devices, Inc.
% Mr. Jacob Jacobson
Chairman
119 Herbert Street
Framingham, Massachusetts 01752

Re: K061425
Trade/Device Name: pureWrist™ Electrocautery Laparoscopic Instrument
Regulatory Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 17, 2006
Received: May 24, 2006

Dear Mr. Jacobson:

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.

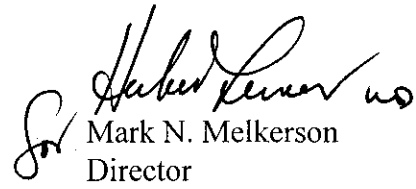
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K061425

Device Name: pureWrist™ Electrocautery Laparoscopic Instruments

Indications for Use:

The pureWrist™ electrocautery laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K061425