K020925

APR 2 9 2003

510K Summary of Safety and Effectiveness

1. Sponsor Name

Endo Surgical Devices, Inc.
4400 Rte 9 So., Suite 1000
Freehold, NJ 07728
Telephone: 732 409-5151

2. Device Name

Proprietary Name: Carbodissecting Endoscope
Common/Usual Name: Intraluminal Artery Stripper
Classification Name: : Intraluminal Artery Stripper

Panel Cardiovascular Device 870.4875
Product Code DWX

3. Identification of Predicate or Legally Marketed Device

- Sobel-Kaplitt-Sawyer Gas Spatula - Becton Dickenson and Company – Preamendments Device
- Endo Surgical Device – Carbodissecting Endoscope
- CardioVacular Concepts, Inc. - Moll Ring Cutter

4. Device Description

The Carbodissecting Endoscope, sterile and single-use, consists of two components:

The spatula is a surgical tool used with carbon dioxide (CO_2) and saline for atherectomy using carbodissection.

The scope is a flexible fiberscope intended for use with the Carbodissecting Endoscope Spatula to provide visual feedback.

5. Intended Use

The Carbodissecting Endoscope is designed for use in intraluminal tissue separation during a femoro-popliteal endarterectomy procedure intended to achieve vascular reconstruction. The device is an adjunctive aid in the separation of vessel layers.

6. Comparison of Technological Characteristics

The Carbodissecting Endoscope is similar to the Sobel-Kaplitt-Sawyer Gas Spatula and the Endo Surgical Devices Carbodissecting Endoscope in function.

The Carbodissecting Endoscope uses carbon dioxide gas to perform the dissection of the vessel whereas the Moll Ring Cutter uses mechanical means. Although the operating principal is different from the Moll Ring cutter, gas dissection has been performed for many years and is well documented. The operating principal is however, the same as the BD Gas Spatula and the Endo Surgical Devices Carbodissecting Endoscope cleared under K013680.

The differences between the BD Gas Spatula and the Carbodissecting Endoscope are the following:

- Integration of the Scope to provide visualization
- CO_2 controls (as opposed to free flow) to limit CO_2 inflow to only during dissection
- Fanned CO_2 from the head for more effective dissection
- Handle for easier manipulation during surgery

The Carbodissecting Endoscope is substantially equivalent to the predicate devices. The intended use, technological characteristics of the device materials and design of the Carbodissecting Endoscope support the concept of substantial equivalence.

7. Performance Testing
The Carbodissecting Endoscope meets the requirements of the following standard:

IEC 601-2-18 Safety of Medical Electrical Equipment: Particular Requirements for Endoscopes

Additional bench testing and biocompatibility testing has been completed on the Carbodissecting Endoscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2003

Endo Surgical Devices, Inc.
c/o Ms. Debbie Iampietro
7 Tiffany Trail
Hopkinton, MA 01748

Re: K020925
Trade Name: Carbodissecting Endoscope
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (two)
Product Code: DWX
Dated: January 28, 2003
Received: February 3, 2003

Dear Ms. Iampietro:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020925

Device Name: Carbodissecting Endoscope

Indications For Use:

The Carbodissecting Endoscope is designed for use in intraluminal tissue separation during a femoro-popliteal endarterectomy procedure intended to achieve vascular reconstruction. The device is an adjunctive aid in the separation of vessel layers.

(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 Cardiovascular Devices
510(k) Number K020925

(Optional Format 3-10-98)

Prescription Use Only