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510 (k) Summary
[as required by 21 CFR 807.92]

APR 1 0 2003

Date Prepared [21 CFR 807.92(a)(1)]

April 18, 2002

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o CooperSurgical Inc.
P.O. Box 2156
Huntington, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor CooperSurgical Inc., 95 Corporate Drive, Trumbull, CT 06611.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are: CooperSurgical Laparoscopic Instruments

Common Name: Monopolar Laparoscopic Instruments, Laparoscopic Grasper, Laparoscopic Cutter, Laparoscopic Dissector, Electrosurgical instruments, Endoscopic Instruments.

Predicate Device [21 CFR 807.92(a)(3)]

- Primus Insulated Forceps – Marlow Surgical Technology – K932832
- Family of Primus Forceps; Graspers and Dissectors – Marlow Surgical Technology – K944563

The subject devices have the same indications for use as the predicates, have stainless steel jaws, are both sold non-sterile, and have monopolar electrocautery capability. The main differences are; change in materials for the handle (carbon fiber versus stainless steel), electrocautery adaptor position has changed from 90 degrees to 45 degrees, and the cleaning method (cleaning port versus disassembly).

Description of the Device [21 CFR 807.92(a)(4)]

These devices represent a family of monopolar laparoscopic instruments that consist of:

- Carbon Fiber Handle (ratcheted and non-ratcheted)
- Stainless Steel Pull Rod attached to a stainless steel jaw
- Insulation material composed of PPSU (PolyPhenylSulfone).

There are various configurations of the jaw (graspers, cutters, and dissectors) to meet the needs of the surgical procedure. The instruments have the capability for monopolar electrocautery to allow for the cutting and coagulation of soft tissue.

These reusable instruments are sold non-sterile. The instruments are packaged in a labeled plastic bag that contains the Directions for Use (DFU).

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Intended Use [21 CFR 807.92(a)(5)]

The devices are designed to manipulate tissue, organs, or bowel during laparoscopic surgery. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate tissue.

Technological Characteristics [21 CFR 807.92(a)(6)]

CooperSurgical Inc. believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The patient contact materials are commonly used in medical devices and have a long history of biocompatibility. The stainless steel 420 is compliant with DIN 17442 standard for Corrosion Resistant Steels for Medical Equipment. The subject devices can withstand 7500 Volts and are compliant with the standard DIN 53483 Dielectric Constant.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Mr. Thomas G. Williams
Director, Quality Assurance
and Regulatory Affairs
CooperSurgical
95 Corporate Drive
TRUMBULL CT 06611

Re: K021237
Trade/Device Name: SEE ATTACHMENT
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: 85 HET
Dated: January 30, 2003
Received: February 3, 2003

Dear Mr. Williams:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

K021237 Enclosure

Device List

Forcep Claw, 10mm, model M695
Grasper, Babcock, 5 mm, model MP759
Grasper, Cone Tip 33 cm, model M683
Scissors, Curved Metzenbaum Rotating, model M689
Models M681, MP756, M686, M682, and M694

5 10(k) Number (if known): K021237

Device Name: CooperSurgical Inc. Laparoscopic Instruments

Indications For Use: The devices are designed to manipulate tissue, organs, or bowel during laparoscopic surgery. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate tissue.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021237