JUN 11 1999

510(K) SUMMARY FOR COOPERSURGICAL, INC.'S INFRARED COAGULATOR

Submitter's Name, Address, Telephone Number, and Contact Person

CooperSurgical, Inc.
15 Forest Parkway
Shelton, Connecticut 06484

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Date Prepared: March 15, 1999

Name of the Device

CooperSurgical InfraRed Coagulator

Common or Usual Name

Infrared Coagulator

Predicate Devices

(1) Redfield Corporation's Redfield Infrared Coagulator for the treatment of hemorrhoids, especially bleeding, non-prolapsed internal hemorrhoids, as a means of hemostasis in the treatment of hemorrhoids by routine excision, or to coagulate external thrombotic hemorrhoids that have been removed; and

(2) CooperSurgical's InfraRed Coagulator for the treatment of genital condylomas (condyloma accuminata) and general warts.

Intended Use

The CooperSurgical IRC is indicated for the treatment of hemorrhoids, especially bleeding, non-prolapsed internal hemorrhoids, as a means of hemostasis in the treatment of hemorrhoids by routine excision, or to coagulate external thrombotic hemorrhoids that have been removed ("collectively referred to as hemorrhoids") through the coagulative necrosis of the mucosa proximal to the base of the hemorrhoid.

Principles of Operation

The Cooper IRC delivers short pulses of visible and infrared light through a small contact tip applicator that is applied to the tissue. This light causes thermal coagulation that results in tissue necrosis. The user sets the pulse duration control knob depending on the depth of the tissue necrosis required. The depth of coagulation is directly related to the pulse length delivered to a given area of tissue. The area(s) to be treated may be locally anesthetized at the physician's discretion.

Contact photocoagulation requires direct contact of the entire optical window of the disposable contact tip. The physician applies light mechanical pressure to the optical window against the tissue to be treated before depressing the activation trigger of the hand piece, waiting at least five seconds between exposures. To achieve coagulation, the user depresses the activation trigger. A built-in digital timer deactivates the lamp automatically according to the pulse duration setting preselected by the physician.

Technical Characteristics

The CooperSurgical IRC consists of the following main components: (1) a console unit; (2) a hand piece; (3) a removable light guide; and (4) a disposable contact tip. The CooperSurgical IRC is essentially the same device as Redfield Corporation's Infrared Coagulator that has already been cleared by FDA for the treatment of hemorrhoids. With the exception of four features, the CooperSurgical IRC is identical to the CooperSurgical IRC that is cleared for the treatment of genital condylomas and general warts.

Summary of the Basis for the Finding of Substantial Equivalence

The safety and effectiveness of the CooperSurgical IRC for the treatment of hemorrhoids is based on FDA's clearance of: (1) Redfield's Infrared Coagulator for the treatment of hemorrhoids; (2) CooperSurgical's InfraRed Coagulator for the treatment of genital condylomas and general warts; and (3) CooperSurgical's testing of the PVC contact tips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

CooperSurgical, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K990852
CooperSurgical InfraRed Coagulator
Dated: March 15, 1999
Received: March 15, 1999
Regulatory Class: II
21 CFR §876.4300/Procode: 78 KNS

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990852

Device Name: CooperSurgical InfraRed Coagulator

Indications for Use:

The CooperSurgical InfraRed Coagulator is indicated for the treatment of hemorrhoids, especially bleeding, non-prolapsed internal hemorrhoids, as a means of hemostasis in the treatment of hemorrhoids by routine excision, or to coagulate external thrombotic hemorrhoids that have been removed through coagulative necrosis of the mucosa proximal to the base of the hemorrhoid.

(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 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990852