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510(k) Summary
CooperSurgical Digital Colposcopy System

1. Sponsor

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CooperSurgical, Inc.
15 Forest Parkway
Shelton, CT 06484
Telephone: (203) 929-6321
Facsimile: (203) 925-0135

Contact Person: John Grasso
Vice President, Operations

Date Prepared: July 11, 1997

2. Device Name

Classification Name: Colposcope, 21 CFR 884.1630, Class II
Proprietary Name: CooperSurgical Digital Colposcopy System

3. Intended Use

The CooperSurgical Digital Colposcopy System combines a standard colposcope with a computer-based Digital Documentation System. The colposcope is intended to permit direct magnified viewing of the tissues of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The Digital Documentation System is intended to provide documentation of the image in the field of view of the colposcope. The image can be viewed on a color monitor, printed on a color printer, or archived for storage and subsequent retrieval.

4. Device Description

The colposcope portion of the CooperSurgical Digital Colposcopy System consists of a stereo microscope with a halogen light source and optional green filter, and is mounted on a mobile base. The Digital Documentation System consists of a CCD camera, an embedded computer, an LCD monitor, a "palm-mouse" pointing

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device, an optional keyboard, and an optional printer. The functional requirements of the Digital Documentation System include:

- Storing digital images for viewing during the colposcopy exam, and for printing and/or later review
- Storing textual information about a patient's medical history related to colposcopy
- Storing textual information about observations seen during a colposcopy examination
- Printing a colposcopy report that integrates images and textual information.
- Implementation of the software green filter.
- A patent-pending procedure to reduce the amount of distracting glare which is often present in pictures of the cervix and other wet tissue.

5. Basis For Substantial Equivalence

The CooperSurgical Digital Colposcopy System is substantially equivalent to the Leisegang Model 1D Colposcope, manufactured by Leisegang Medical, Inc., and the Model 88000 and 89000 Video Colposcopes, manufactured by Welch Allyn, Inc. The Leisegang device received 510(k) premarket notification clearance under K940094 while the Welch Allyn devices were cleared under K955635.

The CooperSurgical, Leisegang and Welch Allyn colposcopes are all intended to permit direct viewing and imaging of the tissues of the vagina and cervix to diagnose abnormalities and select areas for biopsy. While the Leisegang device is video adaptable, the CooperSurgical and Welch Allyn devices contain integrated imaging systems. These imaging systems provide the physician with a means to record pictures of the tissues for review over time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 1998

CooperSurgical, Inc.
c/o Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K972630
CooperSurgical Digital Colposcopy System
Dated: December 24, 1997
Received: December 29, 1997
Regulatory Class: II
21 CFR 884.1630/Procode: 85 HEX

Dear Ms McNamara-Cullinane:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
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): K972630

Device Name: CooperSurgical Digital Colposcopy System

Indications For Use:

The CooperSurgical Digital Colposcopy System combines a standard colposcope with a computer-based Digital Documentation System. The colposcope is intended to permit direct magnified viewing of the tissues of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy. The Digital Documentation System is intended to provide documentation of the image in the field of view of the colposcope. The image can be viewed on a color monitor, printed on a color printer, or archived for storage and subsequent retrieval.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Saltzman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972630

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

(Optional Format 1-2-96)