Section 6.0 510(k) Summary

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510(k) Summary

MAR - 2 1998

K974563

Submitter: Clinical Innovations, Inc.
Name: Wm. Dean Wallace
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Telephone: (801) 268-8200
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Proprietary Name: Colpo Cup
Common/Usual Name: Uterine Manipulator/Injector and Accessories
Classification Name: Uterine Elevator

The legally marketed devices to which equivalence is claimed is the KOH Cup™ Vaginal Fornices Delineator from Cooper Surgical.

Description of the device: The Colpo cup is an accessory to the ClearView Uterine Manipulator that is used to demarcate the cervical/vaginal junction during laparoscopy. This product is a sterile, single patient use device.

Intended use: This accessory is used with the ClearView Uterine Manipulator to demarcate the cervical/vaginal junction during laparoscopy, laparoscopic-assisted vaginal hysterectomy, and other laparoscopic procedures where delineation of the junction is desired.

The Colpo Cup is substantially equivalent to the predicate device because:

It has the same intended uses, namely, to demarcate the cervical/vaginal junction during laparoscopy

It has the same basic technological characteristics as predicate devices, namely, it is a mechanical disc attached to the base of a uterine manipulator

It uses a similar material which has been shown to be biocompatible and to function well in the intended application,

The safety and effectiveness are similar or better than existing devices as demonstrated in the laboratory and clinical testing.

Safety

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Laboratory testing has shown that in the following areas the Colpo Cup is safe:

- Mechanical integrity: laboratory testing and basic design assure that no parts will come loose and be left in the patient.
- Biocompatibility: independent lab testing shows that the material used in the Colpo Cup is safe for this application.

In addition, clinical evaluation verified the safe nature of the Colpo Cup.

Effectiveness

The clinical trials showed that the Colpo Cup was as effective as the predicate device in the following areas:

- ease of use
- device retention

Wm. Dean Wallace

Wm. Dean Wallace, M.D., Ph.D.

1-6-98

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1998

Wm. Dean Wallace, M.D., Ph.D.
President
Clinical Innovations, Inc.
6477 South Cottonwood Street
Murray, UT 84107

Re: K974563
Colpo Cup CVC - 2000
Dated: December 2, 1997
Received: December 5, 1997
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HDP

Dear Dr. Wallace:

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

11.0 Indications For Use

510(k) Number: K974563

Device Name: Colpo Cup (Accessory for Uterine Manipulator)

Indications for use: Demarcation of the cervical/vaginal junction during laparoscopy, laparoscopic-assisted vaginal hysterectomy, laparoscopic bladder surgery and other laparoscopic procedures where delineation of the junction is desired.

(PLEASE NO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Rattling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974563

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)