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AUG 2 2 2003

510(k) Summary

1. Submitter

Intermed Group, Inc.
3550 23rd Ave. S. Ste. 1
Lake Worth, FL 33461

Tel: 561.586.3667
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Contact: George Garamy, Jr. Vice President, Intermed Group, Inc.

Date Prepared: May 12, 2003

2. Device Name

Proprietary Name: Intermed Zoom Colposcope
Common Name: Colposcope
Classification Name: Colposcope (per 21CFR section 884.1630), Class II, 85 HEX

3. Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(K)
Accuscope	Vineland Medical Products	K913365
Wallach Zoom Colposcope	Wallach Surgical Devices	K853389
LM1Z Zoom Scope	Leisegang Medical	K902313

4. Device Description

The Intermed Zoom Colposcope consists of a stereo zoom microscope mounted to a mobile floor stand. A halogen light source with an integrated green filter is also mounted to the stand providing subject illumination.

5. Intended Use

The Intermed Zoom Colposcope is intended for direct magnified viewing of the cervix, vagina, and external genitalia for the purpose of diagnosing abnormalities and selecting areas for biopsy.

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6. Comparison with Predicate Devices

The Intermed Zoom Colposcope, Accuscope(K913365), Wallach Zoom Colposcope(K853389) and LM1Z Zoom Scope(K902313) are intended for direct magnified viewing of the cervix, vagina, and external genitalia for the purpose of diagnosing abnormalities and selecting areas for biopsy.

The Intermed Zoom Colposcope and all of the aforementioned predicate devices utilize technologically similar, commercially available optical systems configured in a like manner in order provide the necessary working distance and magnification for patient observation. In addition, all devices utilize technologically similar 150watt halogen light sources with integrated green filters for subject illumination.

The "Table of Comparison with Predicate Devices" (pg F.1), demonstrates that the technological characteristics of the Intermed Zoom Colposcope and predicate devices are virtually the same. Non-clinical testing has demonstrated that any differences in technological characteristics, does not adversely affect the intended use, performance, or safety of the device. Therefore, the Intermed Zoom Colposcope is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Mr. George Garamy, Jr.
Vice President
Intermed Group, Inc.
3550 23rd Ave. S. Ste. 1
LAKE WORTH FL 33461

Re: K031639
Trade/Device Name: Intermed Zoom Colposcope
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: 85 HEX
Dated: May 12, 2003
Received: May 27, 2003

Dear Mr. Garamy:

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K031639

Device Name: Intermed Zoom Colposcope

Indications for Use:

The Intermed Zoom Colposcope is intended for direct magnified viewing of the cervix, vagina, and external genitalia for the purpose of diagnosing abnormalities and selecting areas for biopsy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031639

Prescription Use ✓
(Per 21 CFR 801.109)