

JUN 19 2002

14 510k Summary

Submitted by: ITL Corporation
P.O. Box 139
41-45 Tennant Street
Fyshwick ACT 2609
Canberra, Australia

Contact Person: William L. Mobbs, BSc, MBA
Director

Date Prepared: March 21, 2002

Proprietary Name: LeeSpec™ Disposable Vaginal Speculum

Common Name: Disposable Vaginal Speculum

Classification Name: Speculum, vaginal, disposable

Predicate Device: Medisul Disposable Vaginal Speculum (K000414)

Description of the Device: The LeeSpec™ Disposable Vaginal Speculum is a non-metal (polystyrene), hand held device used to expose the interior of the vagina.

Intended Use of the Device: To be used by a medical professional to expose the interior of the vagina to facilitate visualization during gynecological or obstetrical procedures. For single use only.

Technical Characteristics: The LeeSpec™ Disposable Vaginal Speculum is made of high impact polystyrene with dual biparting blades. It is manually operated and has a locking (open) and unlocking (release) features, which can be adjusted with one hand. The LeeSpec™ Disposable Vaginal Speculum has the same technological characteristics as and is substantially equivalent to the Medisul disposable Vaginal Speculum (K000414), as shown in the following table:

| Feature | ITL LeeSpec™ Disposable Vaginal Speculum | Medisul Disposable Vaginal Speculum (K000414) |
|----------------------------------|---|---|
| Intended Use | Instrument used by a medical professional to expose the interior of the vagina for gynecological or obstetrical procedures. | Instrument used by a medical professional to expose the interior of the vagina for gynecological or obstetrical procedures. |
| Materials of construction | Polystyrene | Polystyrene |
| Hand held and manually operated? | Yes | Yes |
| Design | Dual, biparting blades | Dual, biparting blades |
| Single use? | Yes | Yes |



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Mr. William L. Mobbs
Director
ITL Corporation
41-45 Tennant Street, Fyshwick
Canberra, ACT 2609
AUSTRALIA

Re: K021017
Trade/Device Name: LeeSpec™ Disposable
Vaginal Speculum
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized
manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: March 25, 2002
Received: March 29, 2002

Dear Mr. Mobbs:

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.

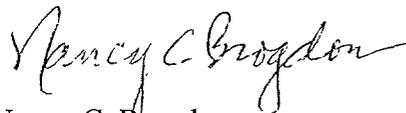
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

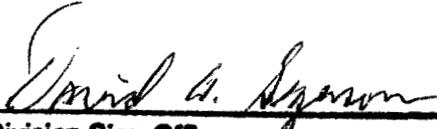
510k Number: K021017

Device Name: LeeSpec™ Disposable Vaginal Speculum

Indications For Use:

The LeeSpec™ Disposable Vaginal Speculum is intended to be used by a medical professional to expose the interior of the vagina to facilitate visualization during gynecological or obstetrical procedures.

Prescription Use



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021017