

DEC 23 1998

K 984211

510 (k) Summary

SUBMITTER'S NAME, ADDRESS, TELEPHONE / FAX NUMBERS AND CONTACT PERSON.

Tennyson P. Tse, Ph.D.
President and CEO
Medscand (USA) Inc.
3930 N29th Avenue
Hollywood, Florida 33020
Tel: (954) 922-2557
Fax: (954) 927-6890

DATE PREPARED

Date: November 20, 1998

NAME OF DEVICE, NAME AND ADDRESS OF SPONSOR

Name of device

Easy-Spec™; Medscand disposable plastic vaginal speculum

Sponsor

Medscand (USA) Inc.
3930 N29th Avenue
Hollywood, Florida 33020

COMMON OR USUAL NAME

Vaginal speculum, disposable speculum, plastic speculum

K 984211

CLASSIFICATION NAME

Speculum, vaginal, disposable

PREDICATE DEVICE

Galenica disposable vaginal speculum

DEVICE DESCRIPTION AND INTENDED USE

The Medscand polystyrene speculum is a **single-use** device to be used by a medical professional to expose the interior of a vagina.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Medscand disposable vaginal speculum is substantially equivalent to the Galenica disposable vaginal speculum in terms of intended use, design, materials, and principles of operation. The dimensions of the Medscand speculum are similar to those of Galenica speculum, which has been cleared by FDA. Galenica speculum has been in clinical use since 1984 and the Medscand speculum since 1993 (in Europe).



DEC 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Tenny P. Tse, Ph.D.
President and CEO
Medscand (U.S.A.), Inc.
P.O. Box 7733
Hollywood, FL 33081Re: K984211
Disposable Vaginal Speculum
Dated: November 20, 1998
Received: November 24, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HIB

Dear Dr. Tse:


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

INDICATIONS FOR USE

510 (k) Number (new): K984211

Device Name:

Medscand Disposable Vaginal Speculum

Indications for Use:

The Medscand disposable speculum is intended to expose the interior of a vagina for gynecological procedures.

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

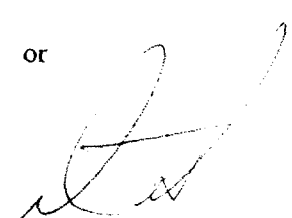
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter-Use

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984211