

ROVERS



MEDICAL
DEVICES BV

FEB - 2 2005 **510(k) Summary**
premarket notification # K043369

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter: Rovers Medical Devices BV
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5347 KV OSS
The Netherlands
Phone: +31 (0)412 64 88 70
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Contact Person: Mr. M.D. Zwart, Managing Director
Rovers Medical Devices B.V.

Device Name

Proprietary Name: Cervex-Brush Combi
Common / Usual Name: Cervical Cell Scraper
Classification Name: Cervical Cytological Endocervical Brush

Equivalent Device

Cervex-Brush®, EndoCervex-Brush, also manufactured by Rovers Medical Devices BV

Device Description

This device consists of handle with a multi-bristled, soft plastic brush mounted on it. The bristles are intended to collect cervical cells for testing and evaluation. For the middle part of the Cervex-Brush Combi the cell-collecting ability of the device is comprised of substantially eccentrically placed parallel plastic bristles, forming a brush head that is connected to the handle. The eccentrically placed bristles are positioned on opposite sides of a square base. The top of the brush is rounded.

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Digital rotation with gentle pressure by way of the handle causes to scrape and remove cytological material simultaneously from the ectocervix and the endocervix. Because the bristles are plastic, wet or humid cells are not absorbed so that the cytological material can easily be transferred to a glass slide or a preservative fluid and sent to the laboratory for evaluation. The device is offered sterile and non-sterile. The Cervex-Brush Combi head is composed of polyethylene, the same material that is used for the Cervex- Brush.

Intended Use Statement

The Rovers Cervex-Brush Combi is intended for the collection of cervical cells for analysis by Pap smear methods and / or by methods for detecting sexually transmitted disease (STD). The Rovers Cervex-Brush Combi is not intended for use in pregnant women.

Technological Characteristics and Substantial Equivalence

The Cervex-Brush Combi is substantially equivalent in terms of intended use, design, manufacturing processes, physical properties, and principles of operation to the Cervex-Brush® and EndoCervex-Brush.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2005

Mr. Ir. M.D. Zwart
Managing Director
Rovers Medical Devices B.V.
Lekstraat 10
5347 KV OSS
THE NETHERLANDS

Re: K043369
Trade/Device Name: Cervex-Brush Combi
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic
specialized manual instrument
Regulatory Class: II
Product Code: 85 HHT
Dated: December 6, 2004
Received: December 8, 2004

Dear Mr. Zwart:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

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MEDICAL
DEVICES BV

Indications for Use

510(k) Number (if known): K043369

Device Name: Cervex-Brush Combi

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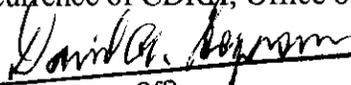
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043369

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