K062433

MAR 16 2007

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Date Prepared:	August 15, 2006
Applicant:	Diamics Incorporated 6 Hamilton Landing, Suite 200 Novato, California 94949 PH (415) 883-0414 FAX (415) 883-0415
Contact Person:	Peter Gombrich, Chief Executive Officer and Chairman
Trade Name:	Diamics CerCol™ Cervical Sample Collection System
Common Name:	Cervical Cytological Sample Collector
Classification Name:	Collector, Cervical Cytological
Classification Status:	CFR 884.4530
Device Classification:	II
Product Code:	HHT
Predicate Device:	MedScand Sample Collection Kit, Cytyc Part # 70124-001, consisting of the Pap Perfect® Plastic Spatula (K832986) and the Cytobrush® Plus GT Gentle Touch (K861389)
Substantially Equivalent To:	The Diamics, Inc. CerCol™ Cervical Sample Collector system, is equivalent to the MedScand Sample Collection Kit, Cytyc Part # 70124-001, consisting of the Pap Perfect® Plastic Spatula (K832986) and the Cytobrush® Plus GT Gentle Touch (K861389)

Description of the Device Subject to Premarket Notification:

This device consists of a reusable handle and a multi-component assembly. The reusable handle provides a means of expanding and manipulating the CerCol™ Cervical Sample Collector so that the surface areas of the endo-cervix, ecto-cervix and transition zones of the cervix are completely contacted by the CerCol™ Cervical Sample Collector tip for the collection, transport, analysis and testing of exfoliated cervical epithelial cells. The CerCol™ Cervical Sample Collector will be available as a single use, non-sterile disposable device and the reusable handle will be available separately, but both components must be used together as part of the CerCol™ Cervical Sample Collector System.

Indications for Use:

The Diamics CerCol Cervical Sample Collector is indicated for the collection of cervical cytology material and its transfer for Pap analysis. The Diamics CerCol Cervical Sample Collector is not intended for use in pregnant women.

The Indications for Use for the Diamics CerCol™ Cervical Sample Collector System has the same intended use and similar technological characteristics in sampling of cervical tissue as compared to the predicate device, the MedScand Sample Collection Kit, Cytyc Part # 70124-001, consisting of the Pap Perfect® Plastic Spatula and Cytobrush® Plus GT Gentle Touch. No new questions of safety or efficacy are raised and information is provided in this submission to demonstrate the safety and efficacy of the devices.

Technical Characteristics:

The CerCol™ Cervical Sample Collector and the predicate device, Cytobrush Plus GT Gentle Touch, are designed to collect and transport exfoliated cervical cells for Pap analysis. The predicate device and the CerCol™ Cervical Sample Collector device in this premarket notification are similar in that both devices are manually manipulated by the hand of the clinician or physician to collect cervical cells. Neither the predicate device nor the Diamics CerCol™ Cervical Sample Collector device is recommended for use in pregnant women.

The predicate device consists of a brush with bristles of various lengths, designed to randomly collect cells from the contours of the cervix. The middle and longest bristles of the predicate device reach deep into the endocervical canal and the shorter bristles touch both the ectocervical and transition zone.

The CerCol™ Cervical Sample Collector is designed with an elastomer tip that conforms to the endocervical canal, and collects cells from the endocervix, the ectocervix and the transition zone. The predicate device is rotated five times by the user. The CerCol™ Cervical Sample Collector is designed to be rotated slightly to thirty degrees by the user.

Once the sample has been collected with the predicate device, the specimen is prepared for laboratory analysis. The sample may be transferred to a slide by rubbing the brush over the surface of the slide. Or, the sample may be transferred to a vial containing liquid preservative by either breaking the brush head off into a preservative vial. In a similar manner, the sample is transferred from the CerCol™ Cervical Sample Collector for analysis by immersing the Collector tip into a similar vial of liquid preservative. Despite the minor differences in collection and transfer of the samples to liquid preservative, the devices are equivalent.

The materials used to manufacture both devices have been tested for biocompatibility and have been determined to be safe for their intended use. No chemicals are used to manufacture the Diamics CerCol™ Cervical Sample Collector device that is subject of this premarket notification.

Performance Data:

Performance testing (bench testing) was performed for the CerCol™ Cervical Sample Collector system to assure that it performs within the predefined parameters. The expansion and retraction action of the handle's tip performs as expected and is adequate for its intended use. Performance testing has been documented, validated and the handle performs as intended and to its specifications.

The expansion of the disposable collector's elastomer tip, the conformance of the expanded tip inside the mock cervix, and the three hundred sixty degree coverage of the endocervical, ectocervical and transition zone performs as expected. Performance testing has been documented, validated and the disposable collector performs as intended and to its specifications.

The CerCol™ Cervical Sample Collector is manufactured under controlled processes. During the manufacturing process, Quality Control (QC) tests are performed. The QC tests are performed on 100% of the CerCol™ Cervical Sample Collector devices as they travel through the production process. A Device History Record (DHR) form is maintained for each lot that is produced.

Basis For Determination of Substantial Equivalence:

The CerCol™ Cervical Sample Collection system manufactured by Diamics Inc. is substantially equivalent to the MedScand Sample Collection Kit, Cytyc Part # 70124-001, consisting of the Pap Perfect® Plastic Spatula and Cytobrush® Plus GT Gentle Touch. Substantial equivalence is based upon the fact that these devices have the same intended uses and similar principles of operation. Substantial equivalence is also based on the fact that the clinical data results demonstrate performance of the subject device is substantially equivalent to the MedScand Sample Collection Kit, Cytyc Part # 70124-001, consisting of the Pap Perfect® Plastic Spatula and Cytobrush® Plus GT Gentle Touch the predicate device.

The clinical data were pooled across two centers resulting in 265 standard collections with 251 satisfactory results and 265 CerCol™ Cervical Sample Collector collections with 251 satisfactory results. The observed rate of satisfactory for the standard method is 99.6% and the observed rate of satisfactory for the CerCol™ Cervical Sample Collector is 98.9%.

Another clinical study, at one center, resulted in 102 CerCol™ Cervical Sample Collector collections with 101 satisfactory results, 99 of which contained endocervical/transformation zone component. The observed rate of satisfactory for the CerCol™ Cervical Sample Collector in this study was 99.0 % and the observed rate of endocervical/transformation zone component was 98.0 %.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Maureen Mende
Director, Regulatory Affairs and Quality Assurance
Diamics, Inc.
Six Hamilton Landing, Suite 200
NOVATO CA 94949

MAR 16 2007

Re: K062433
Trade/Device Name: Diamics CerCol™ Cervical Sample Collector
Regulation Number: 21 CFR §884.4530 (a)(13)
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: March 6, 2007
Received: March 8, 2007

Dear Ms. Mende:

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/industry/support/index.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): K062433

Device Name: Diamics CerCol™ Cervical Sample Collector

Indications for Use: The Diamics CerCol Cervical Sample Collector is indicated for the collection of cervical cytology material and its transfer for Pap analysis. The Diamics CerCol Cervical Sample Collector is not intended for use in pregnant women.

Prescription Use: X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062433