15 K041018

OCT 18 2004

Doctors Research Group, Inc.

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Premarket Notification
510(k) Summary of Safety and Effectiveness
DRG SoftRelease

Submitter:

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Establishment Registration Number: 1226001

Contact Person:

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50 Altair Avenue
Plymouth, CT 06782
(tel) 860-283-1479
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Summary Preparation Date

April 9, 2004

Device Information

Trade name:	DRG SoftRelease
Common name:	Cervical Cell Scraper / Sampler
Classification name:	Cytological Cervical Spatula
Device Classification Panel:	Obstetrical – Gynecological Specialized Manual Instrument
Regulation number:	21CFR Part 884.4530
Class:	II
Product Code:	HHT

510(k) Summary (continued)

Predicate Device

Rovers Spatula	K002520	Rovers Medical Devices BV
Digene Cervical Brush	K971586	Digene Corp.

DRG Device Description

The DRG SoftRelease is a single use, disposable, manual gynecological device intended for the collection of cervical cells for Pap smear analysis and/or for detecting sexually transmitted disease (STD). The device consists of a handle with a release mechanism, a spatula attachment, or a brush attachment. The common handle / release combination allows the attachment of either the spatula or brush for use in cervical or vaginal wall cell collection. The device features an easy release of the cell collector attachments from the device handle.

The brush is composed of bristles joined to a wire shaft. For collecting cervical cells, the brush is inserted into the cervix until only the last row of bristles are visible, rotated once via the handle, and removed from the site for transfer of the cytological material.

The spatula is made of plastic and is curve-shaped, similar to the widely uses Ayre spatula. For collecting cervical cells, the spatula's blunt edge is placed against the cervix, rotated with gentle pressure via the handle, and removed from the site for transfer of the cytological material.

Intended Use

DRG SoftRelease is intended for the collection of cervical cells for Pap smear analysis and/or for detecting sexually transmitted disease (STD).

Basis of Equivalence

The DRG SoftRelease is substantially equivalent to the Rovers Spatula and Digene Cervical Brush based on the indications for use, design, materials, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

Mr. Edward H. Goldman
Director, Quality Assurance
Doctors Research Group, Inc.
50 Altair Avenue
PLYMOUTH CT 06782

Re: K041018
Trade/Device Name: DRG SoftRelease
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HHT
Dated: August 11, 2004
Received: August 16, 2004

Dear Mr. Goldman:

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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Doctors Research Group, Inc.
50 Altair Avenue
Plymouth, CT 06782
(860) 283-1479

Statement of Indications For Use

510(k) Number (if Known): K041018

Device Name: DRG SoftRelease

Indications for use:

DRG SoftRelease is intended for the collection of cervical cells for Pap smear analysis and/or for detecting sexually transmitted disease (STD). This device is not intended for use in pregnant women.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041018