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K980212

P1072

510(k) SUMMARY FOR PRISM TECHNOLOGIES, INC.'S MITYVAC

Submitter's Name, Address, Telephone Number, And Contact Person

Prism Technologies, Inc.
6952 Fairgrounds Parkway
San Antonio, Texas 78238

Contact:	Howard M. Holstein	or	Merle M. Smith
	Hogan & Hartson, L.L.P.		Prism Technologies, Inc.
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Date Prepared

July 7, 1998

Name of the Device

Mityvac

Common or Usual Name

Obstetrical Vacuum Cup

Classification Name

Fetal Vacuum Extractor (21 C.F.R. § 884.4340)

Product Code

HDB

Predicate Device

Gesco International, Inc.'s Vac-U-Nate

K980212

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Intended Use

Prism Technologies, Inc. ("Prism") Mityvac and Gesco International, Inc.'s ("Gesco") Vac-U-Nate are intended to be used to facilitate the delivery of the fetus during childbirth. Both devices are indicated for use during vaginal delivery. The Vac-U-Nate is also indicated for use during caesarean delivery with a transverse incision only. Thus, Prism's Mityvac has the same intended use and as Vac-U-Nate and the Mityvac's only indication is the same as one of this predicate device's indications.

Principles of Operation

Prism's Mityvac and Gesco's Vac-U-Nate are connected to the hospital vacuum or a hand-held vacuum pump using the appropriate regulator. Next, the suction cup is inserted through the vaginal canal during vaginal delivery and attached to the fetus's scalp. After the user confirms that neither maternal tissue nor the placenta are under the cup, the negative pressure is supplied and the user applies traction. The vacuum pressure is released when either the fetus's head is delivered or the fetus's head has not been delivered but certain events have occurred. The user then removes the cup, discards the tubing, and cleans the device. Thus, the principles of operation of Prism's Mityvac and Gesco's Vac-U-Nate are identical.

Technical Characteristics

Prism's Mityvac and Gesco's Vac-U-Nate consist primarily of the following components: (1) a suction cup and shaft; and (2) handle and valve assemblies. Each device's cup and shaft have a positioning reference printed on them and the shaft has three molded ridges on it. Both devices have the same components. These components are composed of the same materials and processed in the same manner. Thus, Prism's Mityvac and Gesco's Vac-U-Nate have the same technological characteristics.

Summary Basis for the Finding of Substantial Equivalence

FDA has granted 510(k) clearance to Gesco's Vac-U-Nate. Prism's Mityvac has the same intended use and very similar indications, principles of operation, and technological characteristics as Gesco's Vac-U-Nate. Therefore, Prism's Mityvac is substantially equivalent to this legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 1998

Prism Technologies, Inc.
c/o Howard M. Holstein
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K980212
Mityvac (Obstetrical Vacuum Cup)
Dated: April 30, 1998
Received: April 30, 1998
Regulatory Class: II
21 CFR 884.4340/Procode: 85 HDB

Dear Mr. Holstein:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980212

Device Name: Prism Enterprises' Mityvac

Indications For Use: To facilitate delivery of a fetus during vaginal deliver

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Ballog

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980212

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)