K020447

APR 12 2002

Attachment 9

510(k) SUMMARY FOR PRISM ENTERPRISES LP
MITYVAC® MERLIN™
Vacuum Assist Delivery System

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

Prism Enterprises LP
6952 Fairgrounds Parkway
San Antonio, TX 78238-4528

Contact:	Frances D. Menard Prism Enterprises LP	or	Merle M. Smith Prism Enterprises LP
Phone:	(210) 256-3113		(210) 520-8051
Facsimile:	(210) 509-7463		(210) 520-8039

Date Prepared

February 8, 2002

Name of the Device

Mityvac® Merlin™

Common or Usual Name

Obstetrical Vacuum Assist Delivery System

Classification Name

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

Product Code

HDB

Predicate Devices

The Mityvac® Merlin™ System is a modification of the Mityvac® MityOne™ Obstetrical Vacuum Assist Delivery System with M-Style® or MitySoft® ("MityOne™").

Intended Use

The Merlin™ System and the MityOne™ System are intended to be used to facilitate the delivery of the fetus during childbirth. These devices are indicated for use during vaginal delivery and caesarean sections. Thus, Merlin™ and MityOne™ have the same intended use and the same indications.

Principles of Operation

The Mityvac® Merlin™ and MityOne™ combine the cup and pump into one unit that allows one clinician to operate the system without an assistant. First, the user opens the sterile package and removes the Merlin™. Next, the user checks the integrity of the system by pressing the cup to the palm of a gloved hand and applying vacuum. Then, the user examines the fetus' presentation and position and inserts the extractor cup through the vaginal canal during vaginal delivery and through the transverse incision during caesarean delivery and attaches it to the flexion point on the fetus' scalp. After confirming that neither maternal tissue nor the placenta is under the cup, the user supplies the negative pressure and applies traction. The user releases vacuum pressure when either the fetus' head is delivered or the fetus' head has not been delivered but certain events have occurred. The user then removes the cup and discards the system per hospital protocol. Thus, the principles of operation of Mityvac® Merlin™ System and Mityvac® MityOne™ System are very similar. The only difference in the principle of operation is that the user of the Merlin™ must puncture the device's Carbon Dioxide ("CO_2") canister to activate its pressure source.

Technical Characteristics

The Mityvac® Merlin™ System is a modification of the cleared Mityvac® MityOne™ System with M-Style® or MitySoft® Bell Cups (K011532). The primary difference between the Mityvac® Merlin™ System and the Mityvac® MityOne™ System is that the Merlin™ System utilizes a CO_2 canister to create the energy for vacuum, while the MityOne™ uses a built-in hand driven pump as the energy source. This difference does not raise new questions of safety or effectiveness.

Summary Basis for the Finding of Substantial Equivalence

The FDA has granted 510(k) clearance to the MityOne™. Merlin™ has the same intended use and indications and very similar principles of operation and technological characteristics as the predicate device. Therefore, Merlin™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Prism Enterprises, Inc.
% Mr. Howard M. Holstein
Partner
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004-1109

Re: K020447
Trade/Device Name: MityVac Merlin, Model 10027
Obstetrical Vacuum Cup
Regulation Number: 21 CFR 884.4340
Regulation Name: Fetal Vacuum Extractor
Regulatory Class: II
Product Code: 85 HDB
Dated: March 15, 2002
Received: March 15, 2002

Dear Mr. Holstein:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K020447

Device Name: Prism Enterprises, Inc.'s Mityvac® Merlin™

Indications for Use: Prism Enterprises, Inc.'s Mityvac® Merlin™ is intended to be utilized to assist a clinician in the delivery of an infant during childbirth. This device is indicated for use during vaginal delivery and Cesarean sections.

(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 C.F.R. 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020447

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