K043614

APR 14 2005

MEDEVCO
The Medical Device Company

510(k) Summary

Submitter Information:

Medevco, Inc.
12201 Merit Drive, Suite 330
Dallas, TX 75251

Contact:

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Date Prepared:

March 10, 2005

Product Name:

This is an accessory to a fetal vacuum extractor, which is a Class II device per 884.4340.
Panel: Obstetrics/Gynecology
Product Code: HDB

Predicate Device:

This device is substantially equivalent to the vacuum indicator features of Kiwi brand fetal vacuum extractor systems marketed by Clinical Innovations, Inc., under K981260, and Mityvac brand vacuum extractor systems marketed by Prism Enterprises (now CooperSurgical) under K011532.

Description:

The VacuLink is a small, battery powered single-use vacuum measuring device. It is connected via plastic tubing to the vacuum chamber of commercial handheld vacuum assisted delivery systems (i.e. Mityvac & Kiwi PalmPump). As a redundant gauge to the Bourdon or stem-type gauges on those devices, it electronically measures the vacuum applied to the fetal head during a vacuum assisted delivery. It connects to the maternal/fetal monitor (i.e. HP, Corometrics and Spacelabs) via electrical cable. The vacuum is numerically displayed in centimeters of mercury (cm Hg). The vacuum data is printed through the uterine activity channel of the maternal/fetal monitor and it

K043614

is permanently stored in the hospital database. The information may also be displayed on a video monitor as well.

The VacuLink incorporates a light sequence of red, yellow, and green. When the VacuLink is initially plugged in all three lights will flash in sequence as a quick test of the internal components. At the successful completion of the test, the green LED illuminates until the VacuLink is disconnected from the maternal/fetal monitor. A flashing yellow LED indicates the battery voltage is low and the VacuLink should be replaced. If the VacuLink has been used previously and is reconnected, the red LED illuminates indicating the VacuLink is no longer operational.

Intended Use:

The VacuLink is intended for obstetric use in the measurement and recording of data related to vacuum-assisted delivery (such as vacuum, number and duration of pulls and number of pop-offs) on the strip chart.

Comparison to Predicate Device:

SUBSTANTIAL EQUIVALENCE COMPARISON			
	VacuLink	Kiwi	Mityvac
Digital display	YES	NO	NO
Permanent record	YES	NO	NO
Disposable	YES	YES	NO
Gauge visible to physician	YES	YES	NO
Ability to display maximum vacuum	YES	YES	YES
Units of vacuum measurement	cm Hg	cm Hg, mm Hg, kPa, in Hg	cm Hg, in Hg
Claimed accuracy/tolerance	at 70 cm Hg = 3.26%	Not published	at 70 cm Hg = 3.27%
Visible display at variable angles	YES	YES	YES
Calibration required by the hospital	NO	NO	YES
Multi-use gauge	NO	NO	YES

The VacuLink contains additional features including:

- Vacuum data recorded on paper strip chart
- Visible display on CRT
- Ability to record maximum vacuum, time at maximum vacuum, total time of vacuum, involuntary releases, reduction of vacuum between contractions, and total number of pulls
- Light sequencing system to confirm functionality of VacuLink

K043614

Performance Data & Conclusions:

Performance testing of VacuLink has been conducted in three main phases:

1. Initial bench testing to compare VacuLink technology to certified reference gauges and predicate vacuum gauges in use at community hospitals.
2. Initial clinical phase (feasibility study)
3. Secondary bench testing on the current configuration of the VacuLink device

Performance testing of VacuLink as well as the reusable handheld vacuum devices reveals that the VacuLink is as accurate as the claimed accuracy of the comparable vacuum gauges. In actual clinical settings, the lack of calibration of the comparable vacuum gauges was such that the VacuLink was more accurate by a factor of 10.

Electrical safety and EMC testing was also performed to demonstrate conformance with established industry standards. Software validation and sterilization process information have also been provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2005

Medevco, Inc.
% Ms. Krista Oakes
Principal
Amica Solutions
2300 McDermott Rd., #200-207
PLANO TX 75025

Re: K043614
Trade/Device Name: Vaculink
Regulation Number: 21 CFR 884.4340
Regulation Name: Fetal vacuum extractor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HDB and HGM
Dated: March 10, 2005
Received: March 11, 2005

Dear Ms. Oakes:

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

510(k) #: K043614

Device Name: VacuLink

Indications for Use:

The VacuLink is intended for obstetric use in the measurement and recording of data related to vacuum-assisted delivery (such as vacuum, number and duration of pulls and number of pop-offs) on the strip chart.

Prescription Use __x____ (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)

David G. Hoyme

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043614