SEP 22 1998

K981260

Section 6.0 510(k) Summary

Submitter: Clinical Innovations, Inc.
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Proprietary Names: Kiwi Fetal Vacuum Extractors VFE-6000S and VFE-6000M
Common/Usual Name: Fetal Vacuum Extractor
Classification Name: Extractor, Vacuum, Fetal

The legally marketed devices to which equivalence is claimed are: Mityvac "M" style vacuum extractor (K890307), Mityvac Super "M" Style vacuum extractor (K943928), Mityvac Obstetric Vac Deliv. Kit w/ Univ. VAC REL (K934011), CMI Velvet Touch Vacuum Extractor (K942725), CMI Vacuum Pump #001C (K881967) and Swift Delivery Product #002 (K970170).

Description of the device: The Kiwi Complete Vacuum Delivery Systems are fetal vacuum extractors having a cup to attach to the fetal head, a handle with which to apply withdrawal force, and a vacuum pump built into the handle of the cup/handle combination. This palm pump includes a method for easily generating a vacuum by pumping the handle with the palm. A vacuum indicator and a vacuum relief valve are also integral to the palm pump. Two styles of cups are available; one of soft silicone (VFE-6000S) and the other of the Malmstrom design (VFE-6000M).

Intended use: Use for fetal vacuum delivery assistance in conditions of: 1) dystocia, 2) uterine inertia, 3) maternal exhaustion (ineffective voluntary effort), or 4) maternal or fetal distress.

The Kiwi Fetal Vacuum Extractors are substantially equivalent to the predicate devices because: they have the same intended uses, namely, use for fetal vacuum delivery assistance, and they have the same basic technological characteristics as predicate devices, namely, a hand pump generating a vacuum that attaches a cup to the fetal head and which has a handle for applying force to assist in the delivery of the fetus. They use the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application.

The safety and effectiveness are similar to existing devices as demonstrated in the laboratory and in clinical testing. Biocompatibility testing shows that the materials used in the Kiwi Fetal Vacuum Extractors are safe for this application. Effectiveness is the same as the predicate devices. The laboratory testing verified the performance in terms of vacuum measurement and device integrity.

Wm. Dean Wallace
Wm. Dean Wallace, M.D., Ph.D.

4-2-98
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Wm. Dean Wallace, M.D., Ph.D.
President
CLINICAL INNOVATIONS
6477 S. Cottonwood Street
Murray, UT 84107

Re: K981260
Kiwi Soft Cup with Palm Pump, Model Nos. VFE-6000M and VFE-6000S (Fetal Vacuum Extractors)
Dated: July 8, 1998
Received: July 10, 1998
Regulatory Class: II
21 CFR 884.4340/Procode: 85 HDB

Dear Dr. Wallace:

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. Additionaliy, 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

11.0 Indications For Use

Device Name: Kiwi Fetal Vacuum Extractor

510(k) Number: K981260

Indications for use:

Standard vacuum extraction

Use for fetal vacuum extraction in conditions of 1) prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate, 2) presumed fetal jeopardy which is not considered to be severe, or 3) elective shortening of the second stage for selected maternal or fetal conditions.

Trial of vacuum extraction

Vacuum delivery should be regarded as a "trial" 1) if there is arrest of descent in the second stage and fetopelvic relationships are considered to be boderline, or 2) in a mid-pelvic extraction when position and station are known.

Vacuum extraction should be abandoned and birth completed by cesarean section 1) if no descent (progress) of the head occurs after 2 tractions, 2) if delivery is not achieved or imminent after 4 tractions, or 3) if the vacuum cup detaches ("pops-off") twice.

(PLEASE NO 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, ENT, and Radiological Devices
510(k) Number K981260

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)