K973942

Premarket Notification (510k) Summary

DEC 12 1997

Submitters Name:	Swift Delivery Products
Address:	6824 Elk Canyon Road, Okla. City, Okla. 73162
Phone:	405-721-8227
Fax:	405-721-8781
Contact Person:	Richard G. Lindsay (Ric Lindsay)
Date:	This summary was prepared 9-21-97
Name of Device:	Swift Delivery Product #003
Common Name:	Vacuum Extractor Cup
Classification Panel:	OB/GYN
Product Code:	85HDB
C.F.R. Section:	CFR - 21 (884.4340)
Device Class:	Class II
Indication Use:	Vacuum Extractor Cup used in child birth
Equivalence to:	K970170 Swift Vacuum Extractor with release valve

Description of the Device: The new product is an improved vacuum extractor cup. The improvement is found in the location of the vacuum tubing attachment point, vacuum release valve and an adaptor for electric vacuum pumps.

Description of use: This vacuum device is used in child birth to allow a physician to assist the mother in a safe vaginal delivery.

Comparison of our 002 Cup and our new 003 Cup: The cup and stem on both products are substantial equivalent. The tubing attachment locations and vacuum release valves are the same. The new #003 product has 6 feet of tubing (instead of 4 feet) and an adaptor to connect to electric pumps.

Non-Clinical Performance Data: A survey was distributed to a select group of physicians in nine states. They indicated this improvement (an adaptor and 2 extra feet of tubing) was needed in our vacuum delivery product.

Conclusions drawn from non-clinical data: The vacuum delivery products now in use can be improved. The new 003 product WILL INCREASE the SAFETY of delivery for the baby, REDUCE the AMOUNT OF TIME of delivery for the mom, provide an IMPROVED CUP for the physician and be allow the hospital to use existing approved electric vacuum pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Mr. Richard Lindsay
President
Swift Delivery Products, Inc.
6824 Elk Canyon Road
Oklahoma City, Oklahoma 73162

Re: K973942
Swift Delivery Tulip Vacuum Cup (Product #003)
Dated: September 21, 1997
Received: September 26, 1997
Regulatory class: II
21 CFR §884.4340/Product code: 85 HDB

Dear Mr. Lindsay:

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 requirement, 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/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): K973942

Device Name: Swift Delivery Product #003 - Vacuum Extractor Cup with Vacuum Release Valve 6 feet of tubing and an Adaptor for electric vacuum pumps.

Indications For Use:

The Indications For Use for this vacuum device in childbirth are the following:
Uterine inertia
Maternal Exhaustion - ineffective voluntary effort
Vertex Presentation
Engagement of the Head
Optional: A. Maternal distress
B. Fetal distress

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Sattler
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973942

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)