AUG 21 1998

K980976

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

P192

Hollister Incorporated
Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Phone (847)680-2849
Fax (847)918-3860

Date Summary Prepared - March 11, 1998

2. Name of Device:

Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap

3. Name of Predicate Device(s)

Ameda Disposable Vacuum Assist Cup, K895700
Mityvac Obstetrical Vacuum Extraction System by Neward Enterprises
Tender Touch Obstetrical Vacuum Delivery Kit by Columbia Medical Inc.

4. Description of Device

The purpose of this premarket notification is to add a fluid retention trap option to the current Ameda Disposable Vacuum Assist Cup in order to collect fluids that may be aspirated during the delivery procedure. The fluid retention trap consists of a housing segment that is constructed of high impact polystyrene and a polyurethane foam filter. The fluid retention trap, when used, is connected to the tubing of the device between the vacuum cup and the vacuum pump.

5. Statement of Intended Use

The Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap is a sterile, single use, device intended to be connected to an externally powered fetal vacuum extractor to aid in vaginal or Cesarean delivery of term or near term infants. The Fluid Retention Trap is intended to collect fluids aspirated during the delivery procedure.

6. Statement of Technological Characteristics of the Device

a. Laboratory Testing: The objective of the laboratory testing was to determine substantial equivalence of the Hollister Disposable Vacuum Assist Cup's Fluid Retention Trap to the predicate devices. Laboratory testing was performed to evaluate fluid handling capacity and resistance to air flow. The results of the laboratory testing support Hollister's claim of substantial equivalence to the predicate devices.

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b. Biocompatibility: The biocompatibility for the Ameda Disposable Vacuum Assist Cup has been documented and cleared in previously submitted 510(k) K895700 "Ameda /Egnell Dolphin Dispo-Soft Vacuum Extractor." The biocompatibility of the Fluid Retention Trap was assessed based on principles and guidelines established by various governmental and standard setting organizations, such as: ISO 10993, International Standard Organization (ISO) Standard; General Program Memorandum #G95-1, U.S. FDA Office of Device Evaluation; United States Pharmacopeia (USP).

Material biocompatibility issues have been addressed based upon biomaterial history or in separate in vitro or in vivo laboratory evaluations using licensed commercial reference laboratories. These evaluations have been contracted either by Hollister or the suppliers of the materials.

Based upon the results of this assessment, the materials used to fabricate the Fluid Retention Trap are considered biocompatible and appropriate for their intended use.

c. Comparison to Predicate Devices: The Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap is substantially equivalent to other devices that are in commercial distribution. This is based on the following:

- The Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap is substantially equivalent in its intended use as a fetal vacuum extractor as described in 21 CFR 884.4340.
- The predicate device, the Ameda Dolphin Dispo-Soft Vacuum Extractor, K895700 and the proposed device are identical in intended use, materials, and manufacturing processes with the exception of the addition of the fluid retention trap option on the proposed device.
- The predicate devices, the Mityvac Extractor Cup System by Neward Enterprises, Inc., and the Tender Touch by Columbia Medical Inc.; and the proposed device are identical in intended use. The predicate and proposed devices include fluid collection capabilities.

7. Conclusion

Based upon the information presented above it is concluded that the proposed Ameda Vacuum Assist Cup with Fluid Retention Trap is safe and effective for its intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 1998

Mr. Joseph S. Takarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Re: K980976
Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap
Dated: July 29, 1998
Received: July 30, 1998
Regulatory Class: II
21 CFR 884.4340/Procode: 85 HDB

Dear Mr. Tokarz:

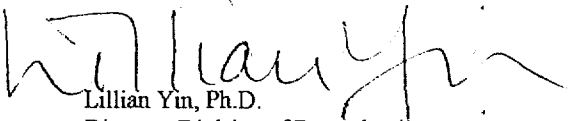
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Hollister Incorporated
Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap

b. Statement of Indications for Use

510(k) Number (if Known): K980976
Device Name: Ameda Disposable Vacuum Assist Cup w/ Fluid Retention Trap

The Ameda Disposable Vacuum Assist Cup with Fluid Retention Trap is a sterile, single use, device intended to be connected to an externally powered fetal vacuum extractor to aid in vaginal or Cesarean delivery of term or near term infants. The Fluid Retention Trap is intended to collect fluids aspirated during the delivery procedure.

Indications For Use:

- Delay in second stage with the fetal head stationed at the outlet; on the pelvic floor; or in the mid-pelvis.
- Delay in the second stage associated with borderline cephalopelvic disproportion
- Fetal distress
- Shortening of second stage labor for fetal or maternal benefit
- Prolapse of the umbilical cord when the cervix is fully dilated

(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 CFR 801.109) (Optional Format 1-2-96)

Robert R Saalfeld
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980976