510(k) Summary

MAY 11 1998 **As Required by 21 section 807.92 (c)**

K974038

1-Submitter Name: A & A Medical, Inc.
2-Address: 4100 Nine McFarland Drive, suite B
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: October 24th, 1997
7-Device Trade or Proprietary Name: " The Aspirator "
8-Device Common or usual name: General Aspiration Pump
9-Device Classification Name: Powered Suction Pump
10-Substantial Equivalency is claimed against the following device:
Substantially equivalent product has been found as approved while searching the FDA web site under product code JCX
Our pump is substantially equivalent to
**K930900 Cook Aspiration Pump from Cook Ob/Gyn*
It is classified under 79JCX: "Powered Suction Pump"

"The Aspirator" is a preammendment medical device introduced into the U.S interstate commerce prior to 28 May, 1976.
It was and is still advertised/labeled rather as an "endometrial aspirator" that follows the product classification of (85HFF) CLASS III device

11-Description of the Device:

" The Aspirator " is a suction pump with a 350mm Hg capacity. It is of low maintenance by design. It provides low noise level. It has an oversized vacuum gauge to allow easy reading. It has a detachable power cord with externally replaceable fuses, and positive detented vacuum lines for fewer leaks. It is available in both 110 and 230 volts. Only UL approved parts are used in the construction.
Recommended accessories are listed below:
Foot Pedal, Silicone Tubing 6 ft, Spare Luer Lock, Metal Tubing Adapter, Spare Glass Reservoir, Neoprene Stopper, and Angled Tube Mounts.

This pump is intended to be used as a general purpose suction pump.

12-Intended use of the device: (Also typed on a separate FDA form as required)

The intended use of this pump is general suction. This is best described under 21 CFR 878.4780, which states that the pump is intended to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter

13-Safety and Effectiveness of the device:

" The Aspirator " is safe and effective as other predicate devices cited above.
It is made out of only UL approved parts.
This is expressed in the tabulated comparison with the other predicate devices
(Paragraph 14 below) and also **documented in the Appendix**

14-Summary comparing technological characteristics with other predicate devices:

Comparison should be done with other predicate devices having ONLY same intended use.
Accordingly, a tabulated comparison with Cook Aspiration Pump is found below.
Also, Equivalency overview chart path is attached

P.S. *Abbreviations used below: E=Equivalent, S=Similar,D=Different, N/A= Not Applicable, DES=Description available, N/I=No Information available, 510(k) Sum=510(k)Summary available, 510(k)=510(k) available, web=fda web printout enclosed*

	TECHNOLOGICAL CHARACTERISTICS																			
	FDA file reference number	Attachments inside Notification	Indications for Use	Target Population	Design	Materials	Performance	Sterility	Biocompatibility	Mechanical Safety	Chemical Safety	Anatomical Sites	Human Factors	Energy used and/or delivered	Compatibility w/ environment & other devices	Where used	Standards met	Electrical Safety	Thermal Safety	Radiation Safety
Cook Aspiration Pump *from Cook Ob/Gyn*	k930900	web 510k approval	E	E	E	S	S	N/A	S	N/A	E	S	E	E	E	S	S	S	S	S

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 1998

Mr. Jihad Mansour
Quality and Regulatory Manager
A&A Medical, Incorporated
4100 Nine McFarland Drive, Suite B
Alpharetta, Georgia 30004-3386

Re: K974038
Trade Name: The Aspirator, 6FT Silicone Tubing, Metal Tubing Adapter, Glass
Regulatory Class: II
Product Code: JCX
Dated: April 1, 1998
Received: April 16, 1998

Dear Mr. Mansour:

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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: The Aspirator

Indications For Use:

The intended use of this pump is general suction. This is best described under 21 CFR 878.4780, which states that the pump is intended to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974038