K994256

FEB 3 2000

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: A & A Medical, Inc.
2-Address: 9370 Industrial Trace
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: December 16th, 1999
7-Device Trade or Proprietary Name: Suction Irrigation Trumpet valve set
8-Device Common or usual name: Suction Irrigation Handpiece
9-Device Classification Name: Laparoscope, general and plastic surgery
10-Substantial Equivalency is claimed against the following device:

- Trump-It II and Magnum 250

11-Description of the Device:

This device consists of the following parts already connected to each other:
- Main Body to control suction and irrigation. A pool suction tip may be connected to the body
- 10 ft Twin tubing to allow for suction and irrigation. The blue color tube allows for irrigation and the clear color tube allows for suction.

A "Y" connector connects the blue tube to two branch tubes (clear color, 12" each). Each branch ends with spike with guard, allowing connection to saline bags. Also, each branch includes a clamp intended to avoid back-flow to the disconnected branch. Clamps may not be used if both branches are simultaneously connected.
An adapter at the end of the other clear color tube allows connection to a suction machine.

12-Intended use of the device:

This device intends to provide pinpoint suction and irrigation to the surgical site during laparoscopic procedures. It is to be used in conjunction with a legally-marketed irrigation pump, irrigant bag or bottle, legally-marketed suction source, and a laparoscopic probe.

13-Safety and Effectiveness of the device:

This device (Suction Irrigation Trumpet valve set) is safe and effective as the other predicate devic cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

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14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that Suction Irrigation Trumpet Valve set is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 973814
Attachments inside notification submission file	510k summary as downloaded from www.fda.gov
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Equivalent
Target population	Equivalent
Design	Equivalent
Materials	Equivalent
Performance	Equivalent
Sterility	Similar
Biocompatibility	Equivalent
Mechanical safety	Equivalent
Chemical safety	Equivalent
Anatomical sites	Equivalent
Human factors	Equivalent
Energy used and/or delivered	Equivalent
Compatibility with environment and other devices	Equivalent
Where used	Equivalent
Standards met	Equivalent
Electrical safety	Equivalent (not applicable)
Thermal safety	Equivalent (not applicable)
Radiation safety	Equivalent (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2000

Mr. Jihad Mansour
Quality & Regulatory Manager
A&A Medical, Inc.
9370 Industrial Trace
Alpharetta, Georgia 30004

Re: K994256
Trade Name: Suction Irrigation Trumpet Valve Set, Model Q65-823
Regulatory Class: II
Product Code: GCJ
Dated: December 16, 1999
Received: December 17, 1999

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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 994256

Device Name: SUCTION IRRIGATION TRUMPET VALVE SET

Indications For Use:

THIS DEVICE IS INDICATED FOR USE IN PATIENTS ELIGIBLE FOR TREATMENT VIA GENERAL LAPAROSCOPIC SURGICAL PROCEDURES

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 994256

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)