510(K) SUMMARY

K071607

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

Submitter: JUN 26 2007

Zhongshan A & J Medical Equipment CO., LTD
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- **Contact Person:**

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Applicant: Zhongshan A & J Medical Equipment CO., LTD
Address: No.3 Shenghui South Road Nantou Town, Zhongshan, City, Guangdong CHINA P.R.C

- **Date Prepared:**

January 15, 2007

Name of the device:

- **Trade/Proprietary Name:** The ASA01 Heavy Duty Suction Pump
- **Common Name:** Powered suction pump
- **Classification**

21 CFR 878.4780 Pump, Portable, Aspiration (Manual or Powered) Class II

Legally Marketed Predicate Device:

K052650 Pioneer U601 Series Aspiration

Description:

Powered suction pumps are described in FDA regulations, 21 CFR 878.4780, as:
"A powered suction pump is an AC-powered device intended to be used to remove infectious materials from wounds or fluids from 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. The FDA classified the device as a class II medical device".

The ASA01 Heavy Duty Suction Pump is an AC-powered, stand-alone device, designed to collection of nonflammable fluid materials in medical applications.

Statement of intended Use:
The ASA01 Heavy Duty Suction Pump is a vacuum suction device designed to remove bodily fluids from the patients' airway or respiratory support system. It is intended for use by trained personnel under the direction of the physician.

Technological Characteristics:
Technologies utilized by the ASA01 Heavy Duty Suction Pump bring forth no new questions of safety and effectiveness. These technologies are also currently being used in the identified predicate device.

Bench performance testing has demonstrated that the ASA01 Heavy Duty Suction Pump is substantially equivalent to the predicate device.

Testing:
Laboratory testing was conducted to validate and verify that the ASA01 Heavy Duty Suction Pump met all design specifications and was substantially equivalent to the predicate device. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. The ASA01 Heavy Duty Suction Pump has also been tested to assure compliance to the requirements of various published standards, including IEC60601-1, IEC60601-1-2, ISO10779-1 and ISO14971.

The ASA01 Heavy Duty Suction Pump is not a software controlled medical device, the software test according the software guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is not applicable.

The accessories which contact the patients directly are provided by the hospital but not the manufacture. All the accessories of the ASA01 Heavy Duty Suction Pump are not contact the patients, the biocompatibility test is not applicable.

The clinical performance test is not applicable

Conclusion:
The conclusions drawn from the testing of the ASA01 Heavy Duty Suction Pump demonstrates that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zhongshan A & J Medical Equipment Co.
% Underwriters Laboratories, Inc.
Mr. Morton S. Christensen
2600 NW Lake Road
Camas, Washington 98607

JUN 26 2007

Re: K071607
Trade/Device Name: ASA01 Heavy Duty Suction Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: May 29, 2007
Received: June 12, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

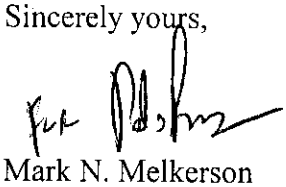
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number (if known): K071607

Device Name: ASA01 Heavy Duty Suction Pump

Indications For Use:

The ASA01 Heavy Duty Suction Pump is a vacuum suction device designed to remove bodily fluids from the patients' airway or respiratory support system. It is intended for use by trained personnel under the direction of the physician.

Prescription Use X
(Per 21 CFR 801 Subpart D)

Over-The Counter Use _____
OR (21 CFR 807 Subpart C)

(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, and Neurological Devices

510(k) Number K071607