9.0 COMPARISONS OF LEGALLY MARKETED DEVICES

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510(k) SUMMARY

510(k) NUMBER: K060182

SUBMITTED BY: Australian Surgical Devices Pty Ltd
2/11 Ponderosa Parade
Warriewood NSW 2102 AUSTRALIA
61-2-9979 4111

SEP - 7 2006

CONTACT PERSON: Mario Kuna
Chief Executive Officer

DATE OF PREPARATION: 17 July 2006 (amended)

NAME OF DEVICE: Suction Irrigator

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery (Regulation Number 21CFR 876.1500, Endoscope and accessories).

TRADE NAME: ASD Tactile Suction and Irrigation System

PREDICATE DEVICE: Applied Medical Resources Corporation, 22872 Avenida Empresa, Rancho Santa margarita, CA-92688 (K003443)

SUMMARY STATEMENT:

The ASD Tactile Suction and Irrigation System, SI-3000T, SI-3000TY and SI-3000TYR, is indicated for use in patients undergoing general laparoscopic surgical procedures. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site. The ASD Tactile Suction and Irrigation System consists of a handpiece equipped with 2 trumpet style valves, a stainless steel probe, and 2 connecting lines of tubing, one designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

The handpiece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments, diameter sizes ranging from 2mm to 5mm to pass through without either a loss of pneumoperitoneum or leakage of fluid. A probe is attached to the handpiece via a threaded connector, thus allowing different sized probes to be attached to the handpiece during surgery.

The suction irrigator is a single use disposable device and is sold sterile.

The ASD Tactile Suction and Irrigation System, SI-3000T, SI-3000TY and SI-3000TYR, is substantially equivalent to the Applied SI Suction irrigator, manufactured by Applied Medical Resources Corporation, 22872 Avenida Empresa, Rancho Santa Margarita, CA-92688. The ASD Suction and Irrigation System, SI-3000T, SI-3000TY and SI-3000TYR, is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2006

Australian Surgical Devices
% Mr. Mario Kuna
Chief Executive Officer
2/11 Ponderosa Parade
Warriewood NSW 2102 Australia

Re: K060182
Trade/Device Name: ASD-Tactile™ Suction and Irrigation System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 7, 2006
Received: August 17, 2006

Dear Mr. Kuna:

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,

For PLO

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

Enclosure

Indications for Use

510(k) Number (if known): K060182

Device Name: ASD-Tactile™ Suction and Irrigation System

Indications for Use: The ASD-Tactile™ Suction and Irrigation System is a sterile, single-use device indicated for use in patients undergoing general laparoscopic surgical procedures.

Prescription use: YES AND/OR Over-The-Counter Use: NO
(21 CFR 801 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 060182