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Attachment 4

510(k) SUMMARY

Submitted by: SSCOR, Incorporated
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Prepared: December 24, 2003

Contact persons: Jesus Gasaway, Director Quality Assurance/Regulatory Affairs
Sam D. Say, President
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Device name: S-SCORT ...Jr® Quickdraw, Model 2400
Common name: Battery Powered Portable Aspiration Pump
Classification name: Powered Suction Pump (21 CFR, 878.4780)

Legally Marketed devices: The SSCOR, Inc. S-SCORT® TEN Model 2100, 510(k) K952632, cleared on June 16, 1995;

The SSCOR, Inc. S-SCORT® Duet Model 2014, 510(k) K945929, cleared on December 22, 1994;

Laerdal Medical Corp., Laerdal™ Suction Unit, 510(k) K840110, cleared on March 12, 1984.

Legally Marketed General Device Description: The S-SCORT® TEN battery powered portable aspirator was developed in 1995 (K952632). It consisted of functional components equivalent to most other portable battery-operated suction devices on the market, i.e., operational controls and circuits, suction pump and motor, and a disposable or reusable canister with tubing and suction tip. The S-SCORT® TEN is intended for portable emergency application environments, where conventional AC house current is typically unavailable. A rechargeable battery powers the S-SCORT® TEN. The entire device is housed on a steel base and lightweight plastic molded chassis with a built-in carrying handle. Although the other two legally marketed devices may look different in outward appearance, the general description is the equivalent.

Legally Marketed Device Configuration: The suction pump component assembly is connected to the collection canister component by means of collapse resistant suction tubing. A longer piece of patient tubing with suction tip is also connected to the canister so as to convey secretions from the patient to the collection canister. All cited legally marketed devices are constructed of components and assemblies arranged in the same fashion.

Operating and Scientific Principles of Legally Marketed Devices: When the assembled device is switched "On", the circuits direct electrical current from the battery to the pump/motor assembly. The pump/motor operates to evacuate air from the collection canister. The resulting sub-atmospheric condition causes air to flow upward from the distal end of the suction tip and into the collection canister. Thus, when called upon to do so, secretions can be carried through the suction tip and patient tubing and deposited into the canister. Additional feature changes to the S-SCORT® TEN were taken into its production efforts toward continuous improvement which are, decreased size and a custom designed molded chassis with integrated carrying handle and canister holder.

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Subject Device Description: The S-SCORT...Jr® Quickdraw device is a design with added benefits of user friendly controls; a battery power level indicator, a custom non-sterile single use disposable canister with integrated suction tip, an equally effective suction pump. The S-SCORT ...Jr® Quickdraw performance is significantly equivalent as the legally marketed devices.

Components: The subject S-SCORT...Jr® Quickdraw consists of a high-speed diaphragm pump powered by an integrated electric motor, an internal 12 VDC sealed lead acid rechargeable battery, and electronic circuit board with controls and signaling light-emitting diodes. All components are assembled into a molded plastic custom chassis. The 12 V battery and 12 V motor make it possible to both operate and charge the device from any 12 VDC source. Charging may also take place by utilizing an external 110 VAC to 9 VDC power converter.

Collection Canister: The S-SCORT...Jr® Quickdraw uses a non-sterile single use disposable canister with integrated suction tip that is blow molded in a transparent plastic of Rigid Polyvinyl Chloride (RPVC) material that has been determined biocompatible (the RPVC does not contain the plasticizer DEHP) to the patient. The canister sidewall has graduation marks that indicate the volume of content in cubic centimeters. The canister has an integrated hydrophobic filter, which acts as a mechanism for overflow protection and capable of bacterial filtration to 99.98% with pore size of 20 microns and .200" in thickness.

Instructions for Use: Directions for use are virtually the same as for the Legally Marketed Suction devices. Users of a suction device should also be well trained in the safe and proper use of medical suction equipment.

Indications for use: Indications for use are very similar to those legally marketed devices cited; as well as more than 10 others sold in the U.S. market. The S-SCORT...Jr® Quickdraw is a non-sterile reusable device, with non-sterile single use disposable canister with integrated suction tip, that is to be used by professional personnel trained in Emergency Care techniques of constant suctioning to clear the airway by removing bodily fluids and particulate matter.

Preparation for Use: The S-SCORT...Jr® Quickdraw will be provided fully assembled and ready for use. Operator/device self-orientation, and device charging as directed are prerequisites to use.

To Use: The user removes the canister from its storage position and installs it in the use position, pre-selects an initial (high/low) suction level, and then switches the device "On". The patient end of the integrated suction tip is ready to suction body fluids and/or particulate matter from a patient's mouth and airway.

Suctioning: The high velocity of the airflow will suction body fluids and/or particulate matter through the integrated suction tip and into the collection canister. In procedures where lower suction is desired, the regulator vent may be adjusted accordingly.

Preparation for Re-Use: After every use the S-SCORT...Jr® Quickdraw exterior surfaces must be wiped clean, refitted with a new disposable canister and connected to a 12 VDC power source for recharging of the internal battery. This is the same procedure as for the legally marketed devices.

Technological Comparison with Legally Marketed Devices:

Similarities - Materials are selected to provide a durable device with equivalent performance to the legally marketed devices. All SSCOR aspirators use a diaphragm vacuum pump. The device can be operated from its internal rechargeable battery, or from a 12 VDC power source. The 12 VDC Cigar lighter adapter, or 110 VAC to 9 VDC power converter, provide power to facilitate charging of the internal battery.

Differences – The S-SCORT...Jr® Quickdraw will use a custom collection canister and a sealed lead acid battery; the legally marketed devices use an aftermarket collection canister, and the Laerdal device uses a Nickel Cadmium (NiCad) battery and a piston pump. The S-SCORT Duet is capable of running from direct 110-230 VAC. The S-SCORT...Jr® Quickdraw uses a combination cabinet/carrying case of size, weight and design different from the legally marketed equivalents.

Test: Tests will be performed using industry standard protocols** to challenge the performance criteria that are typical for this type of medical product. A principle performance criterion are vacuum levels of 300 – 500 millimeters of mercury (mmHg), the time necessary to suction 200cc of vomitus and the ability to function for twenty (20) continuous minutes of operation from its internal battery power source.

Conclusion: The subject S-SCORT...Jr® Quickdraw will be substantially equivalent to its legally marketed versions in construction, indications for use, operating characteristics and performance.

** Industry Standard Protocols:

ISO 10079-1: Medical Suction Equipment-Part 1: Electrically Powered Suction Equipment-Safety Requirements.

ISO 10993-1: Biological Evaluation of Medical Devices

IEC 60601-1: Medical Electrical Equipment- Part 1: General Requirements for Safety.

IEC 60601-1-2: Int'l Electromagnetic Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2004

SSCOR, Inc.
c/o Mr. Daniel W. Lehtonen
Staff Engineer
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K041154
Trade/Device Name: S-SCORT...Jr® Quickdraw, Model 2400
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: April 29, 2004
Received: May 3, 2004

Dear Mr. Lehtonen:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
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): K041154

Device Name: S-SCORT...Jr® Quickdraw, Model 2400

Indications for Use:

The S-SCORT...Jr® Quickdraw, Model 2400 portable battery powered suction pump is a non-sterile reusable device, with a non-sterile single use disposable canister and integrated suction tip, that is to be used by professional personnel trained in Emergency Care techniques of constant suctioning to clear the airway by removing bodily fluids and particulate matter.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041154