DEC 20 1999

K993668

Attachment IX

510(k) Summary

Submitted by:	Laerdal Medical AS Tanke Svilands gt 30 P.O. Box 377 4002 Stavanger Norway	Prepared: 25 October, 1999 Fax: +4751511830
Contact persons:	Mr. Magne Steinset, Acting Technical Product Manager Ms. Hilde Tertnes, Marketing Manager – Airway Products	
Device name:	Laerdal™ Suction Unit Common name: Portable Suction Unit Classification name: Powered Suction Pump (21 CFR, 878, 4780)	
Predicate device:	Laerdal™ Suction Unit (LSU); Pre-amendments device Laerdal™ Suction Unit (LSU); Post-amendments update of above unit K840110 – May, 1984 Laerdal™ Compact Suction Unit (LCSU) K872094 – October, 1987 Laerdal™ Suction Unit 2000 (LSU200) a.k.a. Laerdal™ Premier Suction Unit (LPSU), K950698 – May, 1995	

General device description: The pre-amendment (original) Laerdal™ Suction Unit (LSU) was developed in 1969. It consisted of functional components equivalent to most other portable electrically-operated suction devices on the market, i.e., operational controls and circuits, suction pump with motor, and a disposable or reusable collection canister with tubing. However, the LSU was intended for portable use, in emergency application environments, where conventional AC house current was typically unavailable. Therefore, the LSU was powered by rechargeable batteries, all above components were kept to minimum size and weight, and the entire apparatus housed in a rugged carrying case with built-in handle.

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) suction tubing is also connected to the canister. The latter is the means of conveyance of secretions from the patient to the collection canister. All cited predicate devices are constructed of components and assemblies arranged in the same fashion.

Operating and scientific principals: When the assembled unit is switched "On", the circuits direct electrical current from the battery to the pump/motor assembly. The pump operates to evacuate air from the collection canister. The resulting subatmospheric condition causes air to flow upward from the distal end of the patient suction tubing and into the canister. Thus, when called upon to do so, secretions can be carried through the tubing (suctioned from the patient) and then deposited into the canister. Small features e.g., increased diameter of suction tubing and addition of a shoulder-carrying strap, and others, were taken into LSU production in efforts toward continuous improvement.

Predicate device improvements: In 1984, the Laerdal™ Suction Unit was somewhat redesigned to meet new user needs for extended operating time, larger collection canister and the provision of a suction regulator with gauge. These 510(k) K840110 versions remain in common use.

The 1995 device (LPSU) was a design with fewer parts to assure more rational manufacturing, and an equally effective suction pump at a lower cost. The LPSU design incorporates user convenience features, i.e., direct access controls and tubing storage, and meets user needs for specified performance relating to airflow, vacuum and battery operation time. These 510(k) K950698 versions remain in common use

Subject device description: The 1999 device (LSU4000) is a new more modern, unique solid design witch added benefits of more user-friendly controls, a batery level indicator, and a built in AC adapter. LSU performance is virtually the same as for its predicate designs and configurations.

Components: The subject LSU consists of a high-speed piston pump powered directly by an electric motor, an internal 12 V sealed lead-acid rechargeable battery, an electronic circuit board with controls and signalling light-emitting diodes. All components are assembled into a custom plastic cabinet. The 12 V battery and 8,4 V motor make it possible to both operate and charge the unit from any 12 – 28 VDC, 4 Amp source. Charging may also take place utilizing the internal 110-230 VAC power adapter.

Collection canister: The LSU utilizes a single patient use, standard disposable suction canister that is injection molded in a transparent plastic material. The canister sidewall has graduation marks, which indicate volume of contents. The lid has properly marked connection ports, internal bacterial filter and overflow protection mechanism.

Instruction for use: Directions for use are virtually the same as for the predicate LPSU. 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 identical for the predicate products cited, and also more than 20 others sold in the US market, i.e., to remove obstructing secretions, blood or vomits from a patient's airway, to keep air passages to lungs open to allow ventilation.

Preparation for use: The LSU4000 will be provided assembled and ready for the first use. Operator/device self-orientation, and unit charging as directed, are the prerequisites to use.

To use: The rescuer/user extends the suction tubing, switches the unit on and sets the desired suction level of 80,120, 200, 350, or 500+. The patient end of the tubing, with or without an optional suction tip, is ready to suction blood or vomits from a patient's mouth and airway.

Suctioning: The high velocity of the airflow will suction liquid and particles through the tubing and into the canister. Lower suction and airflow is sometimes desired to reduce the potential for tissue damage on children or when performing tracheal suctioning. This can be obtained by adjusting the vacuum regulator appropriately.

Preparation for re-use: After every use the LSU4000 exterior surfaces must be wiped clean, the unit refitted with a new disposable canister and suction tubing, and be connected to a 12 – 28 VDC or 100 –230 VAC /50-400 Hz power source for recharging of the internal battery. This is the same procedure as for predicate devices.

Technological comparison with predicate Laerdal devices:

Similarities:
Materials are selected to provide a durable unit with equivalent performance to other Laerdal devices. All active pump parts are injection molded. The unit can be operated from its internal rechargeable battery, or from almost any 12-28V DC power source. The 12-28V DC also provides power to facilitate charging of the internal battery.

Differences:
The LSU pump is a high-speed piston pump. Predicates are moderate-speed piston, high-speed piston or high-speed diaphragm types. LSU operates from a sealed lead-acid battery. One predicate utilizes a nickel-cadmium type battery. The LSU4000 can be operated or charged directly from 110 / 230V AC power. All predicates need an external AC power supply. The LSU4000 is a 5-speed pump. Two predicate is a single-speed pumps, another is a two-speed pump. The LSU 4000 apparatus utilizes a combination cabinet/carrying case of size and design different from its predicates. The LSU 4000 has electronics to control flow, vacuum, battery charging and self-test functions. Predicates have mechanical vacuum regulators. For the LSU, the actual vacuum level will be displayed using an LED bar-graph display. Predicates use analogue mechanical vacuum gauges. The battery of LSU can easily be replaced w/o the use of tools. For the predicate devices, tools are required.

Test: Tests will be performed using industry standard protocols* to challenge the performance criteria which are typical for this type of medical product. Principle performance criteria are vacuum levels of 300 – 500 millimeters of mercury (mmHg), airflow of 20 – 30 litres per minute (LPM) and the ability to function for twenty continuous minutes of operation from its internal battery power source. Tests, which are relevant to safety and effectiveness, will be performed simultaneously

Conclusion: The subject Laerdal™ Suction Unit will be substantially equivalent to its predicate versions in construction, indications for use, operating characteristics and performance.

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ISO 10079-1: Medical Suction Equipment – Part 1 Electrically powered suction...
IEC 601-1: Medical Electrical Equipment – Part 1 Gen. requirements for safety
General Services Administration KKK-A-1822C, Federal Specification for Ambulance, para. 3.12.4
ASTM F-29 Standard F 960, Medical and Surgical Suction and Drainage Systems, paras 5.8.1 and 5.8.2

End: Laerdal Suction Unit 4000 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

Mr. Magne Steinset
Acting Technical Product Manager
Laerdal Medical A/S
Tanke Svilandsgt 30
P.O. Box 377,
N-4002 Stavanger
Norway

Re: K993668
Trade Name: Laerdal Suction Unit (4000)
Regulatory Class: II
Product Code: BTA
Dated: October 25, 1999
Received: November 1, 1999

Dear Mr. Steinset:

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.

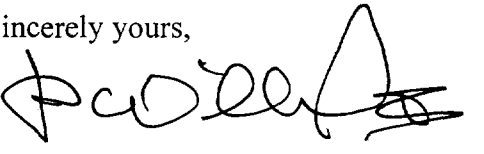
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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): K993668

DEVICE NAME: Laerdal Suction Unit (4000)

INDICATIONS FOR USE:

Indications for use: Indications for use are identical for the predicate products cited, and also more than 20 others sold in the US market, i.e., to remove obstructing secretions, blood or vomits from a patient's airway, to keep air passages to lungs open to allow ventilation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993668