JUL 17 1998

K981602

16. 510(k) Summary

Submitter's Name: Sunrise Medical HHG Inc.
Respiratory Products Division
100 DeVilbiss Drive
Somerset, PA 15501
Allan R. Jones
814-443-7618

Date Prepared: April 30, 1998

Device Name: AC Powered Suction Apparatus FDA Classification JCX

Common or Usual Name: Aspirator

DeVilbiss Model Number: 6305D

Trade Proprietary Name: DeVilbiss Model 6305D Heavy Duty AC Aspirator

Established Registration Number: DeVilbiss # 2515872

FDA Classification: Class II Device

Equivalent Legally Marketed Predicate Device:

Legally Marketed Predicate Devices	510(k) Registration #
Thomas Industries Pump Aspirator Model 1135	K952806

Description of Device:

The DeVilbiss Model 6305D Heavy Duty AC Aspirator is an AC powered vacuum pump assembly designed to be used in conjunction with a collection canister to meet the requirements for oral, nasal and pulmonary aspiration. In terms of function, safety and effectiveness, this device is substantially equivalent to other legally marketed aspirators commonly used for the aspiration of the oral, nasal and pulmonary areas. The DeVilbiss 6305D aspirator is constructed of materials, both metal and plastic, that are similar or identical to legally marketed devices. The unit is designed and manufactured to comply with electrical and mechanical safety standards applicable to this type of device (Underwriter's Laboratory Standard UL1431).

Statement of Intended Use:

The DeVilbiss Model 6305D Heavy Duty AC Aspirator provides a vacuum source for home health care or institutional use. The product is used with a suction catheter or handle to clear secretions from the oral, nasal and pulmonary areas. The intended target population for this device consists of both adult and pediatric patients. The intended environment for use of the product is in the patient's home or within an institutional setting on the order of a physician.

The DeVilbiss Model 6305D Heavy Duty AC Aspirator base unit system will be able to obtain a maximum deadhead vacuum pressure of 22.0 in. Hg and a minimum free flow rate (air) of 25.0 LPM at STP conditions.

The DeVilbiss Model 6305D Heavy Duty AC Aspirator is equivalent in both function and indications for use to the Thomas Industries Pump Aspirator Model 1135 which is a legally marketed device.

Technological Characteristics:

The DeVilbiss Model 6305D Heavy Duty AC Aspirator is equivalent in functional characteristics to the existing legally marketed predicate device. The devices both utilize an AC motor driven vacuum pump compressor to provide a source of vacuum pressure for aspiration. Both of the devices are tested and approved to recognized agency safety standards.

Testing performed on the performance output and suction rate show that the new DeVilbiss Model 6305D Heavy Duty AC Aspirator is substantially equivalent to the existing legally marketed predicate device and that both of these devices will produce similar aspiration treatment.

2.0 Statement of Intended Use

The DeVilbiss Model 6305D Heavy Duty AC Aspirator provides a vacuum source for home health care or institutional use. The product is used with a suction catheter or handle to clear secretions from the oral, nasal and pulmonary areas. The intended target population for this device consists of both adult and pediatric patients. The intended environment for use of the product is in the patient's home or within an institutional setting on the order of a physician.

The DeVilbiss Model 6305D Heavy Duty AC Aspirator base unit system will be able to obtain a maximum deadhead vacuum pressure of 22.0 in. Hg and a minimum free flow rate (air) of 25.0 LPM at STP conditions.

The DeVilbiss Model 6305D Heavy Duty AC Aspirator is equivalent in both function and indications for use to the Thomas Industries Pump Aspirator Model 1135 which is a legally marketed device. The DeVilbiss aspirator is constructed of materials, both metal and plastic, that are similar to or identical to legally marketed devices. The Table of Comparison (Section 4) and the Comparative Performance Evaluations (Section 7) illustrate that in terms of safety and effectiveness, the new DeVilbiss Model 6305D Heavy Duty AC Aspirator is substantially equivalent to the legally marketed Thomas Industries Pump Aspirator Model 1135.

Legally Marketed Predicate Device	**510(k) Registration #**
Thomas Industries Pump Aspirator Model 1135	K952806

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Mr. Allan R. Jones
Project Engineer
Sunrise Medical HHG, Inc.
100 DeVilbiss Drive
Somerset, Pennsylvania 15501

Re: K981602
Trade Name: DeVilbiss Model 6305D Heavy Duty AC Aspirator
Regulatory Class: II
Product Code: BTA
Dated: April 30, 1998
Received: May 5, 1998

Dear Mr. Jones:

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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K981602

DEVICE NAME: DeVilbiss Model 6305D Heavy Duty AC Aspirator

INDICATIONS FOR USE:

The DeVilbiss Model 6305D Heavy Duty AC Aspirator is used primarily to provide a vacuum source for oral, nasal and pulmonary aspiration. The device is used on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981602