SEP 25 1998

K982304

510(k) SUMMARY STATEMENT

Submitter:	**Sunrise Medical HHG Inc.** **Respiratory Products Division** **100 DeVilbiss Drive** **P.O. Box 635** **Somerset, Pa. 15501-0635** **Matt Smith** **814-443-7531** **814-443-7571 Fax**
Date of 510(k) Submittal:	**June 12, 1998**
Classification Name:	**Apparatus, Suction, Ward Use, Portable, AC-Powered**
Product Code:	**JCX**
FDA Regulation:	**878.4780**
FDA Classification:	**Class II**
Common Name:	**Suction Pump/Aspirator**
Proprietary Model #/Name:	**DeVilbiss Suction Unit**
Equivalent to Device(s):	**DeVilbiss 7304 FDA 510(k)#K8720094** **Schuco-Vac FDA 510(k)#K935218**

Description of Device:

The DeVilbiss Suction Unit is a portable AC/DC powered suction pump. It consists of (depending on configuration) a pump unit, collection bottle, relief valve, vacuum gage, bacteria filter, suction tubing, internal battery, and an AC to DC adapter. The device is designed and manufactured to comply with UL 2601-1 and/or CAN/CSA-C22.2 No. 601.1 M90 safety standards.

Intended Use of Device:

The device is to be used to remove fluids from the airway or respiratory support system and infectious materials from wounds. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection bottle. The fluids are trapped in the collection bottle for proper disposal. It is for use on the order of a physician only.

Performance Testing:

The DeVilbiss Suction Unit (depending on configuration) will meet performance standards per ISO 10079-1:1991, Medical Suction Equipment, including vacuum level, flow, construction, life test, and sound level.

Conclusion:

In terms of construction, function, safety, and effectiveness this device is substantially equivalent to other legally marketed suction pumps used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

Mr. Matt Smith
Senior Project Engineer
Sunrise Medical HHG, Inc.
100 Devilbiss Dr.
Somerset, Pennsylvania 15501

Re: K982304
Trade Name: DeVilbiss Suction Unit
Regulatory Class: II
Product Code: JCX
Dated: June 16, 1998
Received: July 01, 1998

Dear Mr. Smith:

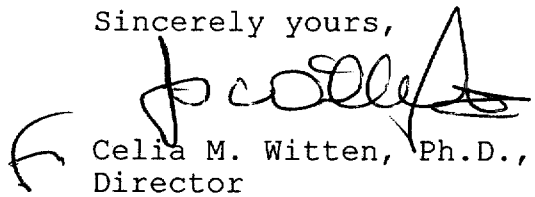
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) Not yet assigned K982304

Device Name: DeVilbiss Suction Unit

Indications for Use:

The DeVilbiss Suction Unit is used to remove fluids from the airway or respiratory support system and infectious materials from wounds. Configurations of the device will be intended for the home, institutional, and field/transport environments. The device is for use only on the order of a physcian or other lincensed practitioner (e.g. EMT-field use).

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982304