K052626 OCT 5 - 2005

## Section 5 - 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

### Submitter

Haemonetics Corporation
400 Wood Road
Braintree, MA. 02184-9114

### Contact

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### Device Name

| | |
|---|---|
| **Proprietary Name:** | *SmartSuction* HARMONY™ |
| **Common Name:** | AC Powered Suction Device |
| **Classification Name:** | AC Powered Suction Pump |

### Predicate Device

The predicate device is the **Medela® Basic 30 Fluid Management System**. The Medela device was cleared under K021368 on 5/15/02.

### Description

Powered suction pumps are described in FDA regulations, 21 CFR 878.4780, as:

> "A powered suction pump is an AC-powered device intended to be used to remove infectious materials from wounds or fluids from patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter. The FDA classified the device as a class II medical device".

The *SmartSuction* HARMONY™ device is an AC-powered, stand-alone device, designed to be used as a suction source to replace wall suction in the hospital operating room to remove fluids and debris from the surgical field during surgical procedures. The *SmartSuction* HARMONY device is designed to be used intra-operatively by trained operating room personnel under the direction of a physician. Therefore, it is to be used as a prescription medical device, which is indicated in the labeling as "Rx only".

## Indications for Use

The *SmartSuction* HARMONY device is an AC-powered suction device intended to be used as a suction source to replace wall suction in the hospital operating room to remove fluids and debris from the surgical field during surgical procedures.

The *SmartSuction* HARMONY device is not intended for endotracheal suction. The *SmartSuction* HARMONY device automatically adjusts suction up to 150 mmHg negative pressure when the suction tip is occluded. Do not use *SmartSuction* HARMONY device as a suction source in any procedure where 150 mmHg of suction could damage underlying tissue.

## Performance Testing – Bench

Haemonetics has conducted testing to verify the electrical safety and performance characteristics as described in the Operation Manual. A detailed list of testing is provided with complete test protocols and reports.

## Substantial Equivalence

The substantial equivalence of the *SmartSuction* HARMONY is supported by its similarities in intended use, technological characteristics, and performance as compared to the currently marketed Medela® Basic 30 Fluid Management System. Both devices have similar technological characteristics. They are similar in design and materials of construction. Both electromechanical devices consist of a vacuum pump and control circuitry. Verification and validation testing has been completed on the *SmartSuction* HARMONY and provide valid scientific evidence to demonstrate the devices are functionally equivalent.

Gabriel J. Muraca, Jr.

Date: September 1, 2005

Gabriel J. Muraca, Jr.
Regulatory Affairs Project Manager
Haemonetics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2005

Haemonetics Corporation
c/o Tamas Borsai
TUV Rheinland of North America, Inc.
12 Commerce Road
Newton, Connecticut 06470

Re: K052626
Trade/Device Name: Haemonetics® SmartSuction HARMONY™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: September 19, 2005
Received: September 23, 2005

Dear Mr. Borsai:

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.

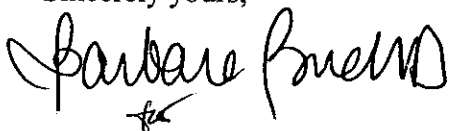
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



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

Enclosure

Section 4 - Indications for Use Statement

Indications for Use

510(k) Number (if known): K052626

Device Name:

Haemonetics® *SmartSuction* HARMONY™

**Indications for Use:**

The *SmartSuction* HARMONY device is an AC-powered suction device intended to be used as a suction source to replace wall suction in the hospital operating room to remove fluids and debris from the surgical field during surgical procedures.

The *SmartSuction* HARMONY device is not intended for endotracheal suction. The *SmartSuction* HARMONY device automatically adjusts suction up to 150 mmHg negative pressure when the suction tip is occluded. Do not use *SmartSuction* HARMONY device as a suction source in any procedure where 150 mmHg of suction could damage underlying tissue.

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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**

HAEMONETICS
COMPANY CONFIDENTIAL

**510(k) Number** K052626