K060790

510(k) SUMMARY

MAY 25 2006

Submitter	Breas Medical AB Företagsvagen 1 SE 435 33 Molnlycke Sweden
Contact Person	Karl-Johan Holm Quality Assurance and Regulatory Affairs Manager Phone: +46 31 868830 Fax: +46 31 868810
Summary Date	March 06, 2006
Name of Device	HA01
Common Name	HA01 Humidifier
Classification Name	Heated Humidifier or humidifier, respiratory gas, (direct patient interface) (21 CFR 868.5450)
Product Code	BTT
Predicate Device	Breas HA50 (K002454)

Device Description:

The HA01 is a humidifier that only can be used together with Breas breathing therapy equipment, such as iSleep or Vivo. It uses pass-over humidification to humidify the air delivered to the patient.

It consists of the following major components:

1 **Water container** – a sealed container with a water capacity of 400 ml. It has one inlet port where the air from the ventilator enters the humidifier and one 22 mm standard conical male outlet port where various non-invasive patient interfaces, such as nasal masks may be connected. It has a detachable lid that is removed when filling water in the container. The water container is attached to other Breas breathing therapy equipment, such as iSleep or Vivo when in use.
Dimensions: W × H × D148 × 155 × 98 mm
Weight; 260 g (empty container)

2 **Electronic heating unit** that via a heating plate heats the water in the water container. Power, 12-30 V DC, max 40 W, is supplied from the Breas breathing therapy unit that the humidifier is connected to. The output from the HA01 unit is controlled by software included in the attached Breas unit. This software, which is a modularized part of the connected unit, controls temperature and it includes alarm supervision.

The Breas HA01 may, together with other Breas breathing therapy equipment such as iSleep or Vivo, be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. It must always be prescribed by a licensed physician.

Intended Use:

The Breas HA01 is a humidifier intended to humidify gases delivered to a patient with a Breas CPAP device or a bilevel ventilator constructed to use an internal mask leak and no active exhalation valve.

Comparison of Use and Technological Characteristics:

The HA01 can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments.

As compared with the cited predicate device, the Breas HA01 has:

Same intended uses

Similar design

Same fundamental scientific technology

The differences that do exist are minimal. The HA01 is intended to be used integrated with other Breas products (e.g. Breas Vivo and iSleep systems). The features are described in the modified device information section 6 and appendix 6 (manuals and sell sheets).

Summary of Performance Testing:

1. Non-clinical testing was conducted to verify that the Breas HA01 is capable of meeting its stated performance specifications and that all Risk Analysis issues have been appropriately addressed. The device passed all tests.

2. Comparative testing to predicate device has been performed, both devices were tested according to ISO 8185. This bench testing confirmed that the HA01 is substantial equivalent to its predicate device.

3. Testing was conducted to demonstrate compliance with applicable requirements in the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the FDA's Division of Cardiovascular, Respiratory, and Neurological Devices and the July 1995 "Draft Reviewer Guidance for Ventilators". The testing included but was not limited to:

- Electrical Safety testing per IEC 60601-1
- Safety and Performance testing per ISO 17510-1
- Medical use humidifiers testing per ISO 8185
- Electromagnetic Compatibility testing (EMC testing)
- Mechanical Safety testing
- Environmental testing
- Functional testing
- Particle matter testing

The testing was performed as an integral part of the development of the Breas Vivo 30, Breas Vivo 40 and Breas iSleep 20 systems.

The device passed all tests.

4. Clinical studies were not required to support a substantial equivalence determination.

Conclusions:

The Breas HA 01 meets its stated performance specifications and criteria outlined in the Reviewer Guidance publications referenced above. We conclude that the device is capable of operating safely in their intended environments and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Mr. Karl-Johan Holm
Quality Assurance & Regulatory Affairs Mananger
Breas Medical AB
Företagsvagen 1
Molnlycke
SWEDEN SE 435 33

Re: K060790
Trade/Device Name: Breas, Model HA01
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: April 25, 2006
Received: May 1, 2006

Dear Mr. Holm:

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.

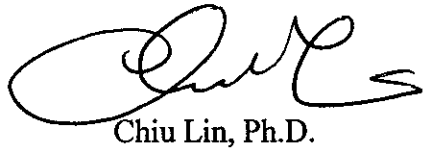
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number (if known): K060790

Device Name: Breas HA01

Indications for Use:

The Breas HA01 is a humidifier intended to humidify gases delivered to a patient with a Breas CPAP device or a bilevel ventilator constructed to use an internal mask leak and no active exhalation valve.

Prescription Use **X** AND/OR Over-The-Counter Use –
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K060790