

K023641

NOV 27 2002

**Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda HMEF Mini**

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 28, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda HMEF Mini

COMMON NAME:

Disposable Heat and Moisture Exchanger and Bacteria/Viral Filter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

CAH Breathing Circuit Bacterial Filter 868.5260

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda HMEF Mini is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF500 (K021265).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use and indications for use for the modified device are the same as the predicate.

There has been no change to the fundamental scientific technology from the predicate.

The HMEF Mini incorporates a hygroscopically treated HME media and electrostatic filter media into a housing made of translucent plastic.

Dimensions and Materials

- Diameter: 45 mm
- Length: 64 mm
- Housing: PP Polypropylene
- HME-element: PU Polyurethane impregnated with calcium chloride CaCl₂
- Filter: PP and acrylic fibers

Filtration efficiency:

- Filtration efficiency viral 99.98 %
- Filtration efficiency bacterial 99.999 %

The HMEF Mini is for use in small adult and pediatric patients in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.

It incorporates standard fittings for-

- 15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask
- 15 mm OD x 22 mm ID fitting to connect to the breathing circuit Y-piece
- A gas sampling port – female luer port with cap to allow sampling of expired CO₂ gases

The modifications to the device are:

The Datex-Ohmeda HMEF Mini has the following differences when compared to the Datex-Ohmeda HMEF500 predicate device:

The devices differ in length, weight, dead space, moisture output, moisture loss, breathing resistance and minimum tidal volume

The main differences between the Datex-Ohmeda HMEF Mini and the predicate Datex-Ohmeda HMEF500 (K021265) are due to fact that the size of the Datex-Ohmeda HMEF Mini is less than the Datex-Ohmeda HMEF500 (K021265). This makes the dead space of the HMEF Mini lower than HMEF500. The HMEF Mini can be used with smaller patients compared to the HMEF 500. The predicate HMEF 500 has a bacterial filtration efficiency (BFE) of 99.9999999% when measured in CAMR lab. UK. Now both HMEF500 and HMEF Mini have a BFE of 99.999%. The bacterial filtration efficiency differs because the measurements were made in different laboratories (Nelson lab. and CAMR). The HMEF Mini and the predicate HMEF 500 have the same (99.98%) Viral Filtration efficiency (VFE). The predicate HMEF500 has exactly the same viral filtration efficiency as before, only the stated accuracy has increased from 99.9% to 99.98%.

The changes in the labels and instructions for use were made to add the specifications and name of the new device to the IFU. No changes in the warnings, cautions or contraindications have been made.

INTENDED USE as required by 807.92(a)(5)

Indication for use: The HMEF Mini is a disposable single-use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF Mini is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda HMEF Mini is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF500 (K021265).

The Datex-Ohmeda HMEF Mini has the following similarities to the Datex-Ohmeda HMEF500 predicate device:

- have the same indicated use
- have the same fundamental scientific technology and use the same operating principle
- are manufactured using the same processes
- constructed of identical materials
- Both the HMEF Mini and predicate HMEF 500 give efficient protection against transfer of bacteria / viruses between patients, personnel and equipment
- Filtration efficiency against virus
- Filtration efficiency against bacteria

The Datex-Ohmeda HMEF Mini has the following differences when compared to the Datex-Ohmeda HMEF500 predicate device:

- The devices differ in length, weight, dead space
- The devices differ in Moisture output, Moisture loss, Breathing resistance and Minimum Tidal Volume

The main differences between the Datex-Ohmeda HMEF Mini and the predicate Datex-Ohmeda HMEF500 (K021265) are due to fact that the size of the Datex-Ohmeda HMEFMini is less than the Datex-Ohmeda HMEF500 (K021265). This makes the dead space of the HMEF Mini lower than HMEF500. The HMEF Mini can be used with smaller patients compared to the HMEF 500. The predicate HMEF 500 has a bacterial filtration efficiency (BFE) of 99.9999999% when measured in CAMR lab. UK. Now both HMEF500 and HMEF Mini have a BFE of 99.999%. The bacterial filtration efficiency differs because the measurements were made in different laboratories (Nelson lab. and CAMR). The laboratories have different sensitivities in measurement devices. The previous laboratory (CAMR) uses different micro-organisms at higher challenge levels. The HMEF Mini and the predicate HMEF 500 have the same (99.98%) Viral Filtration efficiency (VFE). The predicate HMEF500 has exactly the same viral filtration efficiency as before, only the stated accuracy has increased from 99.9% to 99.98%.

In summary, the Datex-Ohmeda HMEF Mini, described in this submission is substantially equivalent to the predicate HMEF 500 (K021265).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda HMEF Mini complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- ISO 9360:1992
- ISO 5356-1:1996
- ISO 594-1:1986
- ISO 594-2:1998
- EN 980:1996
- EN 1041:1998
- EN 13014
- ASTM F 1054-8721

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda HMEF Mini as compared to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2002

Mr. Joel C. Kent
Manager, Quality Assurance and Regulatory Affairs
Datex Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K023641

Trade/Device Name: Datex-Ohmeda HMEF Mini
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: October 28, 2002
Received: October 30, 2002

Dear Mr. Kent:

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.

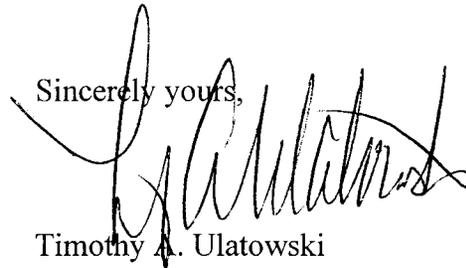
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Page 2 – Mr. Kent

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 (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023641

Device Name: Datex-Ohmeda HMEF Mini

The HMEF Mini is a disposable single-use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF Mini is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only.

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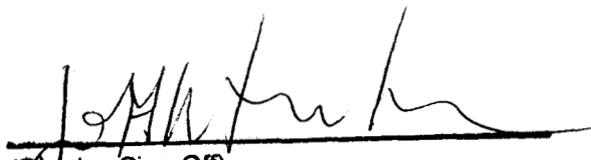
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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