K072136

JUL 15 2008

Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

Name:	Wilfried Krömker Medizintechnik GmbH
Address:	Nordring 27a 31675 Bückeburg, Nordring 27a
Phone: **FAX:**	++ 49 5722 905441 ++ 49 5722 21780
Contact Name: **Email:**	Dr. Thomas Ley, Assistant Director t.ley@kroemker-medtec.de
Summary Date:	June 8, 2008
Common Name:	Ultrasonic Nebuliser
Proprietary Name:	Ultra Neb 2010 Ultrasonic Nebuliser
Classification Name:	Nebulizer (Direct Patient Interface)
Classification Regulation No:	868.5630
Classification Panel:	Anaesthesiology
Product Code:	CAF

Predicate Device:

- **Predicate Device:** Ultra-Neb 99 Ultrasonic Nebulizer
- **510K Number:** K872826
- **Manufacturer:** DeVilbiss Healtcare, Somerset PA (division of Sunrise Medical)
- **Classification:** Nebulizer (direct patient interface)
- **Product Code:** CAF

Reason for Submission: New Device

Description of Device

The Ultra-Neb 2010 Ultrasonic Nebulizer is a reusable ultrasonic nebulizer for the inhalation therapy of saline solution, or of aerosol medications. It is a desktop or pole stand mounted device, containing a nebulizing chamber that can be filled by the user. Power input is provided by AC mains.

Intended Use

The Ultra-Neb 2010 Ultrasonic Nebulizer is a nebulizer that will be used with patients for whom doctors have prescribed inhalation therapy or medication for nebulisation for their lung or airway disease.

Indications for Use

The Krömker Medizintechnik Nebulizer Model Ultra-Neb 2010 is designed to aerosolize saline solution and liquid medication by ultrasonic energy. A single patient use medication cup is available for use with medications.

The device is intended for use on adult and pediatric patients who have been prescribed inhalation therapy, sputum induction, or medication for nebulization. The device is intended for use in hospitals, hospital-type facilities, nursing home, sub-acute institutions, and home environments.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Technology

The Ultra-Neb 2010 Ultrasonic Nebulizer device utilizes similar technological characteristics as the predicate devices. Ultrasonic Nebulizers utilize an ultrasound transducer to energize the water in the chamber and aerosolize the liquid, which may contain prescribed medication for inhalation therapy. The device is connected to the patient via a therapy hose, which may be connected to various industry-offered mouthpieces and masks (not supplied with the device).

Non-Clinical Tests Submitted:

The device was tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility (EMC), environmental temperature and humidity, and shock and vibration. The Ultra-Neb 2010 Ultrasonic Nebulizer passed all of the tests.

Performance testing was conducted in comparison with the predicate devices for dead volume, aerosol particle characteristics and aerosol output. The device met specified requirements and was comparable to the applicable specifications of the predicate devices.

The materials utilized in the device comply with biocompatibility requirements appropriate for the intended use.

Clinical Tests Submitted: None

Conclusions

The function of the Model Ultra-Neb 2010 Ultrasonic Nebulizer is substantially equivalent to the predicate device. Laboratory and standards compliance tests are provided to support the safety and performance of the device.

As described above, all of the testing demonstrates that the Wilfried Krömker Medizintechnik GmbH Ultra-Neb Model 2010 Ultrasonic Nebulizer is as safe and effective and performs in a manner equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wilfried Krömker Medizintechnik GmbH
C/O Mr. Stephen H. Gorski
President
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

JUL 15 2008

Re: K072136
Trade/Device Name: Krömker Medizintechnik Nebulizer Model Ultra-Neb 2010
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: April 11, 2008
Received: April 14, 2008

Dear Mr. Gorski:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Krömker Medizintechnik Nebulizer Model Ultra-Neb 2010

Indications for use:

The Krömker Medizintechnik Nebulizer Model Ultra-Neb 2010 is designed to aerosolize saline solution and liquid medication by ultrasonic energy. A single patient use medication cup is available for use with medications.

The device is intended for use on adult and pediatric patients who have been prescribed inhalation therapy, sputum induction, or medication for nebulization. The device is intended for use in hospitals, hospital-type facilities, nursing home, sub-acute institutions, and home environments.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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)

N. Maly for M. Husband

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

510(k) Number: K072136