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K994352

510(K) SUMMARY

Side Draft Neb-U-Mist® Nebulizer
Section 20

1.0 Date

December 21, 1999

2.0 Submitter

Hudson Respiratory Care, Inc.
27711 Diaz Road
Temecula, California 92590

3.0 Contact Person

Jeannie Denning
Regulatory Affairs Manager

4.0 Telephone

(909) 676-5611, ext. 1232

5.0 Proprietary Device Name

Side Draft Neb-U-Mist® Nebulizer

6.0 Classification Name

Nebulizer

7.0 Common Name

Nebulizer

8.0 Predicate Device

Hudson RCI 6350 Home Care Nebulizer, 510(k) number K930525

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510(K) SUMMARY
Side Draft Neb-U-Mist® Nebulizer

Section 20

9.0 Device Description

The Hudson RCI Side Draft Neb-U-Mist® Nebulizer employs the Bernoulli Effect in order to transform the solution of liquid medication into tiny particles that can be carried in a gas mixture to the patient. The Bernoulli Effect - the phenomenon of internal pressure reduction with increased stream velocity in a fluid – causes the lowering of lateral pressure around the stream of gas to draw liquid up a capillary tube. When the liquid reaches the top of the capillary tube it comes into contact with the stream of gas, it is then shattered into small particles (approximately 3 to 5 microns). These particles are then forced against a baffle that reduces the average size of the particles that will be delivered to the patient by removing the larger particles. The larger particles settle inside the Nebulizer as a result of gravity and inertia, returning mist to liquid to repeat nebulization process. The smaller particles are then administered as the patient inhales.

10.0 Intended Use

The Hudson RCI Side Draft Neb-U-Mist® Nebulizer is a non-sterile, single patient use, Disposable Small Volume Nebulizer device designed to be used for intermittent aerosol therapy to deliver hydrating agents or other prescribed solutions for inhalation. The Hudson RCI Side Draft Neb-U-Mist® Nebulizers intended to treat bronchial spasms, or airway obstruction, associated with diseases such as asthma, chronic bronchitis, and emphysema.

11.0 Patient Population

The Hudson RCI Side Draft Neb-U-Mist® Nebulizer is intended for use with pediatric and adult patients.

12.0 Comparison of Technological Characteristics

Hudson RCI Side Draft Neb-U-Mist® Nebulizer is substantially equivalent to the predicate device in design and function, (Hudson RCI Cat. No. 6350 Nebulizer.) Particle Size testing of the mist generated during the nebulization process was performed on both devices utilizing commonly used medications. (Albuterol Sulfate, Metaproternol Sulfate and Tobramicyn.) Test results indicate that the Hudson RCI Side Draft Neb-U-Mist® Nebulizer and the predicate device both generate particle sizes in the desired range of 0.5µm – 5.0µm. Residual testing for both the predicate and proposed devices demonstrated that the devices are substantially equivalent.

12.1 Materials

The Hudson RCI Side Draft Neb-U-Mist® Nebulizer and the predicate device are made of similar materials of construction which are common to those used in industry for Nebulizer products. The proposed Hudson RCI Side Draft Neb-U-Mist® Nebulizer device is comprised entirely of Polypropylene, while the predicate device utilizes K-Resin for the Jar, Polystyrene for the jar lid, impingement dome and capillary tube.

12.2 Device Design

The Hudson RCI predicate and the proposed device have similar designs. Each product consists of small volume jar, lid, capillary tube and dome on which particles are shattered. Both products function at flows of 6-8 LPM of gas, and both devices are designed with flat exterior bottoms to facilitate steady filling of the jar. Both devices have etched markings to reflect the maximum fill level, although the proposed device indicates the level of fluid in incremental markings and the predicate device reflects Maximum fill. Both devices connect to an oxygen source however, the predicate device is designed with an oxygen connection port at the bottom of the jar, while the proposed device has an oxygen connection port on the side of the lid. The gas enters the predicate device through the bottom of the jar where it hits a dome which shatters the particles into therapeutic size. In the case of the proposed device, the Oxygen enters the device through the cap where it meets with medication that has been drawn up the capillary tube. The medication is forced against a baffle on the lid, where the particles are shattered into therapeutic size.

13.0 Conclusion

Based on the information contained in this 510(k) submission, Hudson RCI has determined that the proposed Hudson RCI Side Draft Neb-U-Mist Nebulizer and the predicate Hudson RCI Cat. no. 6350 Home Care Nebulizer are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Jeannie Denning
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula, CA 92589-9020

Re: K994352
Side Draft Neb-U-Mist Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: December 21, 1999
Received: December 23, 1999

Dear Ms. Denning:

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 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). 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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K994352

Device Name: Hudson RCI Side Draft Neb-U-Mist Nebulizer

Indications for Use

Indications for Use

The Side Draft Neb-U-Mist Nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. This device is for single patient use and is not intended for reprocessing.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K994352

Prescription Use X OR Over-the-Counter Use ____

Per 21 CFR 801.109

(Optional format 1-2-96)