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K980024

Shining World Healthcare Co., LTD
Shinmed SW-966 Ultrasonic Nebulizer

Submitter Information:

Shining World Healthcare Co., Ltd.
PO Box 32, Lu-Chou
Taipei, Hsien, Taiwan R.O.C.

510(k) Summary Prepared by:

Carolann Kotula
Official Correspondent for MSI
c/o mdi Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021

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Date 510(k) Summary Prepared: December 22, 1997

Name/Classification of the Device:

Classification Name: Nebulizer, 21 CFR 868.56300

Common Name: Ultrasonic Nebulizer

Proprietary Name: Shinmed Model SW-966 Ultrasonic Nebulizer

Classification/Panel: Nebulizers have been classified by the Anesthesiology Panel as Class II devices.

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Identification of the Legally Marketed Device to which the Submitter Claims Equivalence: Comparative Information: The Shimed Ultrasonic Nebulizer Model SW-966 is substantially equivalent in intended use, principal of operation, performance as the MicroSonic nebulizer, manufactured by Medel Electronmedicali, Parma, Italy and legally marketed in the United States as the Lumiscope under K924081. The mask and mouthpiece are identical to the oxygen mask legally marketed by Dadsun Corp., LTD under K851466.

Description of the Subject Device: The Shinmed Ultrasonic Nebulizer is a standard direct current ultrasonic nebulizer system designed to atomize medications into gases for patient direct breathing. The device consists of a table-top high-frequency main unit which provides an occillation frequency of 1.63 MHz. The 30 cc disposable medicine cup in the main unit. A mask or mouthpiece is attached to the main unit with a flexible hose. The patient breaths the medicine through the mask or mouthpiece.

Intended_Useof the Subject Device: The Shinmed Ultrasonic Nebulizer is intended to spray liquid medications in aerosol form into gases that are directly delivered to the patient.

Technological Characteristics of the Subject Device: There are no significant differences in the characteristics of the subject devices and the predicates. Nebulizer Characterization Studies completed on the subject device and the predicate found both nebulizers produced MPS distribution data below the (FDA suggested) maximum of 10 microns. The amount of drug delivered by each of the nebulizers was similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Ms. Carolann Kotula
Shining World Health Care Co., Ltd.
c/o MDI Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021

Re: K980024
Shinmed SW 966 Ultrasonic Nebulizer
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: August 24, 1999
Received: August 26, 1999

Dear Ms. Kotula:

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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Shinmed SW-966 Ultrasonic Nebulizer

Indications for Use:

The Shinmed Ultrasonic Nebulizer is intended to spray liquid medications in aerosol form into gases that are directly delivered to the patient.

(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
510(k) Number K980024

Prescription Use ✓ OR Over the Counter Use _____