K090207

510(k) Summary
807.92(c)

JUN 18 2009

SPONSOR **807.92(a)(1)**

Company Name: Diagnostic Devices Inc.

Company Address: 93030 Harris Corner Parkway
Suite 450
Charlotte, NC 28269

Telephone: 704-285-6400
Fax: 704-285-6475

Contact Person: Rick Admani

Summary Preparation Date: February 5, 2008

DEVICE NAME **807.92(a)(2)**

Trade Name:	DDI Ultrasonic Nebulizer System
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer (Direct Patient Interface)
Regulation Number:	CFR21 868.5360
Product Code:	CAF
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Omron Healthcare Inc.	Micro Air Vibrating Mesh Nebulizer	K062263
Health & Life Co., Ltd.	Ultrasonic Nebulizer System Model HL 100	K081738

DEVICE DESCRIPTION **807.92(a)(4)**

The DDI Ultrasonic Nebulizer System is a mesh screen ultrasonic nebulizer that operates in an identical fashion as other mesh screen nebulizers. The device creates aerosols of liquid medication by ejection of droplets from a mesh vibrated at ultrasonic frequencies and provide fine particles to the patient's lungs. The DDI Ultrasonic Nebulizer System is powered by a cable connecting to a 115 VAC power source with the AC adapter or two AA alkaline batteries.

DEVICE INTENDED USE **807.92(a)(5)**

Indicated Use: The DDI Ultrasonic Nebulizer System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.

Patient Population: The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

Environment of Use: Home, hospital, and sub-acute care

Contraindications: None

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Parameters	New Device	Predicate Device	Predicate Device
Device Name	**DDI Ultrasonic Nebulizer System**	**Health & Life Co. Ultrasonic Nebulizer System Model HL 100**	**Omron Micro-Air Vibrating Mesh Nebulizer**
510(k) Number	N/A	K081738	K062263
Indented Use Statement	The DDI Ultrasonic Nebulizer System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.	The Ultrasonic Nebulizer System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.	The Ultrasonic Nebulizer System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient
Target Population	Pediatric and adult	Pediatric and adult	Pediatric and adult
Environment of use	Home, hospital, sub-acute care	Home, hospital, sub-acute care	Home, hospital, sub-acute care
Mode of Operation			
Anatomical Site	Mouth	Mouth	Mouth
Mode of Operation	Ultrasonic	Ultrasonic	Ultrasonic
Energy Type	Electricity	Electricity	Electricity
Energy Source	115 VAC or 2 AA Alkaline batteries	115 VAC or 2 AA Alkaline batteries	115 VAC or 2 AA Alkaline batteries
Battery Life	4 Hours	4 Hours	4 Hours
Aerosolization Element	Metal Mesh	Metal mesh	Metal Mesh
Nebulizing method	Vibrating mesh	Vibrating mesh	Vibrating mesh
Nebulization rate	0.2 ml/min	0.2 ml/min	0.25 ml/min
Particle Size (MMAD)	Approx 5 microns	Approx 5 microns	Approx 5 microns
User Interface			
Patient Connector	Mouthpiece Optional Mask	Mouthpiece Optional Mask	Mouthpiece Optional Mask
Patient Interface	Hand-held	Hand-held	Hand-held
Use	Single patient	Single patient	Single patient
Physical Description			
Dimensions (in	4.3" x 2.2" x 1.7"	4.3" x 2.2" x 1.7"	4.1" x 2.1" x 1.5"
Weight	98 grams (Excluding batteries)	98 grams (Excluding batteries)	97
Portable	Yes	Yes	Yes
Reservoir (mL)	8 ml maximum	8 ml maximum	7 ml maximum
Ultrasonic	Yes	Yes	Yes

Nebulizer			
Nebulizer components cleanable	Yes	Yes	Yes
Materials of Construction			
Materials	Plastic and metal	Plastic and metal	Plastic and metal

NONCLINICAL AND CLINICAL TEST 807.92(b)

Electrical Safety
The electrical performance of the DDI Ultrasonic Nebulizer System meets the requirements of the following standards:

IEC 60601: 1988 + A1: 1991 + A2: 1996
EN 60601-1:1990 +A1: 1993 + A2: 1995 +A13: 1996
EN 60 601-1-2:2001

CONCLUSION 807.92(b)(3)

The DDI Ultrasonic Nebulizer System and the predicate devices use a micro pore mesh vibrating at ultrasonic frequencies to produce aerosol. All of the performance parameters of the devices are statistically identical, and do not raise any new safety or efficacy. All devices are similar in:

- Intended Use
- Materials
- Design
- Technological Characteristics

The DDI Ultrasonic Nebulizer System introduces no new questions concerning the safety or effectiveness and is thus substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Diagnostic Devices Incorporated
C/O Mr. E. J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K090307
Trade/Device Name: DDI Ultrasonic Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 5, 2009
Received: March 20, 2009

Dear Mr. Smith:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Susan Runner, D.D.S., M.A.
Acting Division 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: DDI Ultrasonic Nebulizer System

Indications for Use:

The DDI Ultrasonic Nebulizer System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.

The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

Prescription Use __√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: k 090807