



July 23, 1990

DIVERSATRONICS, INC.  
Marianne Tanton  
Director, Quality and Regulatory Affairs  
620 PKWY.  
BROOMALL, PA 19008  
US

Re: K896536

Trade/Device Name: Pharmatronics Nebulizer  
Regulation Number: 21 CFR 868.5630  
Regulation Name: Nebulizer  
Regulatory Class: Class II  
Product Code: CAF  
Dated: June 20, 1990  
Received: June 25, 1990

Dear Marianne Tanton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.  
Pamidimukkala -S

for Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

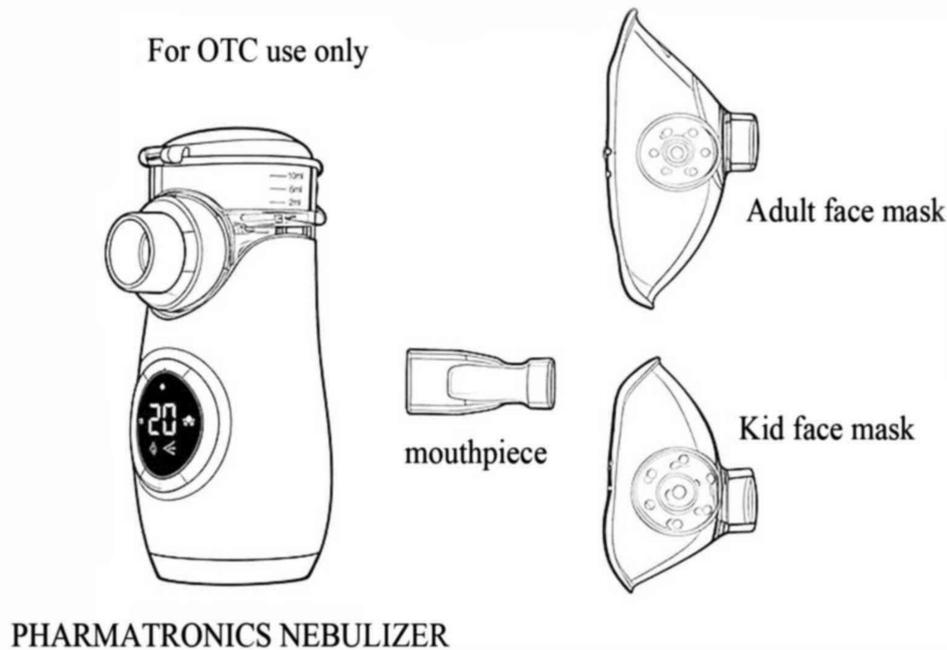
K896536

Device Name

PHARMATRONICS NEBULIZER

Indications for Use (Describe)

The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients. The device is designed to aerosolize medication for inhalation in the home care environment. The nebulizer is a single patient use device.



Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## Section 5 – 510(k) Summary

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Prepared: 22-July-1990

### 1. Submitter

DIVERSATRONICS, INC.  
620 PKWY.  
BROOMALL, PA 19008  
Contact: Marianne Tanton  
Director, Quality and Regulatory Affairs

### 2. Device Name

Trade Name:	Pharmatronics Nebulizer
Common Name:	Portable Nebulizer
Classification Name:	Nebulizer 21 CFR 868.5630
Regulatory Class:	II
Product Code:	CAF

### 3. Predicate Device

Disposable Nebulizer - K761299  
MCGAW RESPIRATORY THERAPY

The predicate device has not been subject to a recall.

### 4. Reference Device

Pharmatronics Nebulizer – K896536  
DIVERSATRONICS, INC.

The predicate device has not been subject to a recall.

### 5. Device Description

The Pharmatronics Nebulizer is a small portable nebulizer designed to deliver aerosolized medications for inhalation to the respiratory system. The device is intended to be used by pediatric (ages 2 years and above) and adult patients in home care settings. The Pharmatronics Nebulizer is a single patient use device and may be used for multiple treatments. This device is not used with a specific drug nor is it distributed with such drugs.

## **Section 5 – 510(k) Summary**

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### **6. Principle of Operation**

The proposed device is a vibrating mesh nebulizer that uses low frequency vibration to create aerosol and delivers aerosolized medication to the lower respiratory tract by using a vibrating mesh to create aerosol and provide fine particles to the patient's lungs. The mesh plate has holes to create low velocity aerosol. The proposed device is a portable size, convenient to hold, and ability to detect the amount of medications available. The medication container capacity is 8ml maximum.

### **7. Indications for Use**

The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients. The device is designed to aerosolize medication for inhalation by a patient in the home care environment. The nebulizer is a single patient use device.

### **8. Comparison to predicate device**

The Pharmatronics Nebulizer and Disposable Nebulizer (K761299), are identical in purpose, function, core technology and method of operation. Only minor differences exist between the Pharmatronics Nebulizer and predicate, which do not affect the safety or effectiveness of the subject device. Table 1 provides a comparison of the subject and predicate devices.

## Section 5 – 510(k) Summary

**Table 1: Comparison to Predicate Device**

Element of Comparison	Pharmatronics Nebulizer (Subject Device)	Disposable Nebulizer (Predicate Device - K761299)
Indications for Use	The Pharmatronics Nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients. The device is designed to aerosolize medication for inhalation by a patient in the home care environment. The nebulizer is a single patient use device.	The Disposable nebulizer is a single patient use device. The device is a vibrating mesh nebulizer that uses low frequency vibration to create aerosol and delivers aerosolized medication to the lower respiratory tract by using a vibrating mesh to create aerosol and provide fine particles to the patient's lungs. The mesh plate has holes to create low velocity aerosol. It can be used in home care settings.
Principle of Operation	Vibrating Mesh Nebulizer	
Environment of use	Home	
Patient population	Adult and pediatric patients (ages 2 years and above)	All
Single Patient Use	Yes	
Aerosolization	Continuous during inhalation and exhalation	Built-in mode selector for breath actuated or continuous mode
Type of device	Reusable Device for single patient use, non-sterile	
Manufacturing process	Plastic molding	
Flow rate	4-8 LPM	2.75 – 8 LPM
Maximum Fill Volume	8 mL	

## 9. Performance Data

### 9.1 Aerosol Characterization

Aerosol characterization testing for the subject (Mouthpiece and Mask) and predicate device was conducted in accordance with the relevant sections of the CDRH Guidance Document "Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators" (FDA/CDRH – 1993). Testing was performed at both low and high supplied air flow rates. The table below reflects data at 8 l/min supplied air flow rate to the nebulizer and 15 l/min flow rate through the cascade impactor. The table below also includes data from testing conducted with the medium mask, however, the nebulizer was also tested with small and large masks, which demonstrated similar performance to the medium mask.

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**Table 2: Performance Data**

Aerosol Characteristics	Particle Characterization	
	Continuous Nebulizer, with Mouthpiece (Subject Device) (Job # 1668)	Continuous Nebulizer, with Mask* (Subject Device) (Job # 1655)
Total Mass (µg)	1494.4 ± 38.4 Albuterol <sup>†</sup> 602.5 ± 34.5 Ipratropium Bromide <sup>††</sup> 338.9 ± 29.9 Budesonide <sup>†††</sup>	1604.3 ± 28.1 Albuterol <sup>†</sup> 689.5 ± 16.3 Ipratropium Bromide <sup>††</sup> 357 ± 19.3 Budesonide <sup>†††</sup>
Total Output Rate (µg/s)	7.1 ± 0.1 Albuterol <sup>†</sup> 1.9 ± 0.2 Ipratropium Bromide <sup>††</sup> 0.9 ± 0.1 Budesonide <sup>†††</sup>	3.7 ± 0.2 Albuterol <sup>†</sup> 1.1 ± 0.1 Ipratropium Bromide <sup>††</sup> 0.5 ± 0.0 Budesonide <sup>†††</sup>
Fine Particle Fraction (0.98-5.39 µm aerodynamic diameter) (%)	72.4 ± 0.4 Albuterol <sup>†</sup> 72.0 ± 0.4 Ipratropium Bromide <sup>††</sup> 64.6 ± 1.4 Budesonide <sup>†††</sup>	71.1 ± 0.9 Albuterol <sup>†</sup> 69.3 ± 2.8 Ipratropium Bromide <sup>††</sup> 65.9 ± 2.2 Budesonide <sup>†††</sup>
Fine Particle Mass (µg)	1081.2 ± 30.2 Albuterol <sup>†</sup> 433.9 ± 23.3 Ipratropium Bromide <sup>††</sup> 218.8 ± 17.0 Budesonide <sup>†††</sup>	1150.1 ± 19.7 Albuterol <sup>†</sup> 478.1 ± 22.3 Ipratropium Bromide <sup>††</sup> 235.0 ± 6.6 Budesonide <sup>†††</sup>
Fine Particle Output Rate (µg/s)	5.1 ± 0.1 Albuterol <sup>†</sup> 1.4 ± 0.1 Ipratropium Bromide <sup>††</sup> 0.6 ± 0.1 Budesonide <sup>†††</sup>	2.7 ± 0.1 Albuterol <sup>†</sup> 0.8 ± 0.1 Ipratropium Bromide <sup>††</sup> 0.3 ± 0.0 Budesonide <sup>†††</sup>
Particle Size (MMAD)	2.6 µg Albuterol <sup>†</sup> 2.7 µg Ipratropium Bromide <sup>††</sup> 4.2 µg Budesonide <sup>†††</sup>	2.4 µg Albuterol <sup>†</sup> 2.5 µg Ipratropium Bromide <sup>††</sup> 4.1 µg Budesonide <sup>†††</sup>
GSD	2.1 Albuterol <sup>†</sup> 2.1 Ipratropium Bromide <sup>††</sup> 1.9 Budesonide <sup>†††</sup>	2.2 Albuterol <sup>†</sup> 2.3 Ipratropium Bromide <sup>††</sup> 1.9 Budesonide <sup>†††</sup>

<sup>†</sup> Albuterol Sulfate Inhalation Solution, 833µg/ml

<sup>††</sup> Ipratropium Bromide Inhalation Solution 250µg/ml

<sup>†††</sup> Budesonide Suspension for Inhalation 0.25mg/ml

\* Disposable Aerosol Mask Assembly – Medium Mask

## Section 5 – 510(k) Summary

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### 9.2 Biocompatibility Testing

Biological endpoints applicable to an externally communicating device, tissue contact by way of gas pathway with permanent duration (> 30 days) are listed below. All *in vitro* and *in vivo* studies were performed by an independent source and included the following battery of tests: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Genotoxicity and Extractables/Leachables with a Biological Risk Assessment.

#### Summary of Biocompatibility Testing Conducted

ISO Standard	Biological Endpoint
10993-5	Tests for In Vitro Cytotoxicity
10993-10	Tests for Irritation and Skin Sensitization
10993-11	Tests for systemic toxicity (Acute Toxicity)
10993-3	Tests for genotoxicity (Bacterial Reverse Mutation Study and Mouse Lymphoma Assay)
10993-12	Sample preparation and reference materials
10993-17	Establishment of allowable limits for leachable substances
10993-18	Chemical characterization of materials

### 9.3 Dry Gas Pathway Testing

Testing pertaining to the dry gas pathway and associated risk assessments/conclusions were conducted by an independent source. Testing included the following assessments:

- Emissions of volatile organic compounds (VOCs)
- Fine particles (particulate matter PM2.5)
- Inorganic gases (ozone, CO<sub>2</sub>, and CO)

## 10. Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance data.

## 11. Conclusion

The non-clinical data demonstrates that the Pharmatronics Nebulizer is as safe and as effective as the predicate and therefore substantially equivalent to the predicate device.