



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY - 7 2004

Mr. Stephen W. Briggs III, R.R.T, RCP  
President  
B & B Medical Technologies, Incorporated  
6731 32<sup>nd</sup> Street, Suite B  
North Highlands, California 95660

Re: K030396  
Trade Name: Omni~Neb™ and Omni~Max™ Nebulizers  
Regulation Number: 21 CFR 868.5630  
Regulation Name: Nebulizer (Direct Patient Interface)  
Regulatory Class: II  
Product Code: CAF  
Dated: April 8, 2004  
Received: April 12, 2004

Dear Mr. Briggs:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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): K030396

Device Name: Omni-Neb and Omni-Max

### Indications For Use:

#### Omni-Neb™

This device is to be used under medical supervision in hospitals, nursing homes, extended care facilities and outpatient clinics. The Omni-Neb™ Nebulizer is a low flow continuous nebulizer to be used to deliver aerosolized medications for up to four hours via direct patient interface on spontaneous breathing patients. Patient population: Asthma, Pneumonia, COPD, or any other conditions in which sympathomimetic amines, parasympathetic amines, Steroids, or other appropriate medications would be aerosolized. The Omni-Neb™ requires 45-55 psig source gas of Oxygen or Air.

#### Omni-Max™

This device is to be used under medical supervision in hospitals. The Omni-Max™ Nebulizer is to be used to deliver aerosolized medications in conjunction with Heliox therapy to spontaneous breathing patients. Patient population: Asthma, Pneumonia, COPD, or any other condition in which sympathomimetic amines, parasympathetic amines, Steroids, or other appropriate medications would be aerosolized, and adjunctive Heliox would be beneficial. The Omni-Max™ requires 45-55 psig of Oxygen source gas. 10 liters/minute of 80/20 Heliox is added via auxiliary gas port.

Prescription Use xx  
(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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K030396