DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 9 1998

Bremed Italia
c/o Mr. Mark Hebenstreit
1337 Rockwood Forest Drive
Arnold, MO 63010

Re: K982043
BRENEB
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: September 27, 1998
Received: October 6, 1998

Dear Mr. Hebenstreit:

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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the

Food and Drug Administration (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 the 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,

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

INDICATIONS FOR USE STATEMENT

510(k) Number: Pending K982043

Device Name: BRENEB HAND HELD NEBULIZER
Indications for Use:

This product is a hand held nebulizer that is used to provide aerosolized broncho dialator medication to persons with asthma or emphysema. The device creates aerosolized particles of the prescribed medication via interface with a nebulizer compressor.

The compressor creates air pressure which is forced up disposable tubing and into the hand held nebulizer. Inside the hand held nebulizer, the medication is forced via a vacuum created by the air pressure up into the baffle which mixes the medication with the air, creating the aerosolized particles.

The patient inhales the aerosolized prescribed medication via a mouthpiece which is attached to the hand held nebulizer. The treatment lasts as per his/her physicians orders.

This product contains the exact same technological characteristics of similar devices currently on the market. The product functions exactly as these similar devices.

The product is designed with similar performance characteristics as devices currently on the market. The performance of the device allows it to be used in conjunction with various nasal and oral masks that are currently in distribution in the United States and Europe.

The components found within this product are safe and common items.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XXXXX **OR** **Over-The-Counter**_____

Mark Kramer

(Division **Sign-Off**)
Division of **Cardiovascular, Respiratory,**
and Neurological **Devices**
510(k) Number K982043