



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1998

Mr. Gregg Gaskins
Nidek Medical Products, Inc.
3949 Valley East Industrial Drive
Birmingham, AL 35217

Re: K980551
Silenzio Delta Continuous Positive Airway Pressure System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: August 14, 1998
Received: August 19, 1998

Dear Mr. Gaskins:

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 (Pre-market 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.

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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

510(k) Number: **K980551**

Device Name: **Silenzio Delta Continuous Positive Airway Pressure System.**

Indications For Use:

The Silenzio Delta is intended for the treatment of Obstructive Sleep Apnea (OSA) in adult patients 30 kg and over.

Silenzio Delta has three modes of operation. In CPAP mode, treatment is carried out by applying a continuous positive airway pressure through a nasal mask. In the BPAP mode, the pressure during expiration is lower than during inspiration, as prescribed by the physician. In a third mode, a minimum breathing rate can be set between 0 to 25 BrPM. The operation is identical as in BPAP mode, but if the patient fails to make an inspiratory effort within the interval set by the minimum BrPM control, the device will cycle to the pressure support level to deliver the breath to the patient based on the minimum BrPM setting.

The Silenzio Delta can be used to administer oxygen by using external oxygen tank and bleeding oxygen into the patient circuit. This therapy is not metered or otherwise regulated. Patient monitoring must be performed to ensure effective administration of oxygen therapy.

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980551

✓ Prescription Use

- OTC