SEP 2 2 2004

510(k) Summary of Safety and Effectiveness
Airways Development, LLC
Clarissa™ Infant nCPAP Cannula (K032922)

Submitted By:	Airways Development, LLC 209 North 14th Street Kenilworth, NJ 07033
Date:	September 20, 2004
Contact Person:	Robert Landis Vice President, Product Development Airways Development, LLC 209 North 14th Street Kenilworth, NJ 07033 Tel: (908) 931-1333 Fax: (908) 931-0034
Proprietary Name:	Clarissa Infant n-CPAP Cannula
Common Name:	Infant CPAP Nasal Cannula
Classification Name and Reference:	Ventilator, Continuous, Facility Use 21CFR 868.5895
Device Product Code and Panel Code:	CBK Anesthesiology Panel
Predicate Devices:	Argyle CPAP Nasal Cannula (K811409) Neotech Binasal Airway (K792018) Medicomp CPAP Nasal Cannula (K861280) Hudson Infant Nasal CPAP Cannula (K871157) Ackrad Infant Nasal Cannula (K895031)

Device Description:

The Clarissa Infant nCPAP Cannula is a soft hollow medical grade silicone coaxial pouch with protruding silicone cannula tips that fit into the infant's nares. Continuous flow circulates through the coaxial pouch under positive pressure from which the patient breathes via the cannula. The distal end of the pouch has a swivel adapter with three external ports and one external port. One external port is for pressure and the other two are in-flow and out-flow ports which are bi-directional. The internal port on the swivel adapter is the connection for the internal tube leading to the proximal cannula to minimize dead space.

Intended Use:

The Clarissa Infant nCPAP Cannula is intended to be used for the administration of continuous positive airway pressure (CPAP) on continuously monitored neonatal and infant patients in the hospital/institutional environment.

Technological Characteristics

The Clarissa™ Infant nCPAP Cannula is a patient interface designed to be used with continuous flow CPAP circuits or ventilators in the continuous flow CPAP mode. The cannula tips are inserted into the nasal passage to affect a seal for the continuous flow to produce CPAP.

The air input end has a swivel adapter that connects to 10mm breathing circuits. During actual use the wide part of the pouch lays on the infant's forehead and the narrow portion extends down to the nasal openings where cannula tips protrude out of the pouch at a 90 degree angle. The device has built-in attachment loops to facilitate attachment to head bonnet.

The device material is a soft expandable and flexible medical grade silicone. The only materials to contact the patient are the silicone cannula and polyurethane foam head bonnet.

Performance Data

The test data submitted demonstrates that the proposed Clarissa Infant nCPAP Cannula performance is essentially equivalent to the above listed predicate devices. Testing completed shows devices provide essentially equivalent flow resistance and dead space volume.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Airways Development, LLC
C/O Mr. Richard J. Larkin
Regulatory Affairs Consultant
R.J. Larkin Consulting, Incorporated
209 North 14th Street, P.O. Box
Kenilworth, New Jersey 07033-0496

Re: K032922
Trade/Device Name: Clarissa™ Infant nCPAP Cannula
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 14, 2004
Received: September 15, 2004

Dear Mr. Larkin:

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,

Susan Runner

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): K032922

Device Name: Clarissa™ Infant nCPAP Cannula

Indications For Use: The Clarissa Infant nCPAP Cannula is intended to be used for the administration of continuous positive airway pressure (CPAP) on continuously monitored neonatal and infant patients in the hospital/institutional environment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K032922