K030747

APR 2 2 2004

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Section 3 Non-Confidential Summary of Safety and Effectiveness

Proprietary or Trade Name:	**Prodose** AAD System
Common / Usual Name:	Jet Nebulizer
Classification Name:	Nebulizer, Direct Patient Interface
Official Contact:	Dr Neil Purcell Profile Therapeutics plc Heath Place, Bognor Regis West Sussex, PO22 9SL, UK
Predicate Device	HaloLite AAD System, K 981772, K991685 AutoNeb K935693 MiniMed Model 508 K990801

Device Description

The **Prodose** AAD system is a single patient reusable portable pneumatic jet nebulizer, designed to deliver a precise and reproducible dose of aerosolized liquid medication. The device consists of a base unit containing a dedicated air compressor and a hand-piece containing a pressure transducer, a microprocessor control system, a medication chamber, a baffle, and a mouthpiece. The pre-set dose volume is stored on a disc, which has a bi-directional inductively coupled transponder with data storage capacity in a non-volatile memory (EEPROM) embedded in the disc.

The **Prodose** AAD system analyses the patient's breathing pattern to determine the acrosol pulse time. The system then pulses aerosol during patient inspiration only. The length of each pulse of acrosol is calculated according to the measured inspiratory time. **Prodose** continues to monitor the breathing pattern throughout treatment in order to adapt to changes in the breathing pattern. When the pre-set dose of medication has been delivered, the system indicates that the treatment is complete.

1. Intended use
A jet nebulizer system designed to aerosolize commonly prescribed liquid medication (except Pentamidine) for inhalation by the patient.

2. Environment of Use –
Home care, nursing home, sub-acute institutions or hospital.

3. Patient Population –
Patients requiring nebulized drug delivery via a mouthpiece.

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Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and a legally marketed predicate device. The most significant attributes have been listed.

Attribute	HaloLite AAD System K981772, K991685	Prodose AAD System
Use		
Intended to nebulize drugs	Yes	Yes
Jet Nebulizer System	Yes	Yes
Synchronized Delivery of Nebulized drug	Yes	Yes
Drug Delivery on demand	Yes	Yes
Used in hospitals, home care, nursing home, sub-acute institutions	Yes	Yes
Single Patient reusable	Yes	Yes
Design		
Flow Rates	6 LPM	6 LPM
Gas Source - Compressed Air	Yes	Yes
Software Driven	Microprocessor	Microprocessor
Mode of Operation	Breathe activated	Breathe activated
Drug delivery triggered by	Patient Inhalation	Patient Inhalation
Used with Mouthpiece	Yes	Yes
Materials		
Materials in Contact with Patient	Polycarbonate Polyethylene	Polycarbonate Polyethylene
Packaging		
Provided clean, non-sterile	Yes	Yes
Performance Standards / Specifications		
Applicable under Section 514	None	Various

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Differences Between Other Legally Marketed Predicate Device

The main differences between the intended device, **Pro*dose*** AAD System, and the predicate device HaloLite AAD System are -

1. The **Pro*dose*** AAD System provides a user-friendly LCD graphic display to show visual information such as "treatment completed", "error message codes" and "pause mode" compared with the flashing LED lights used in HaloLite for visual feedback.

2. The **Pro*dose*** user interface is a microprocessor disc. This permits pre-set dose information to be stored in the disc rather than relying on users selecting the correctly colored button on the front of HaloLite. The microprocessor disc also prevents multiple doses being delivered by inappropriate button pressing, as the compressor needs to be restarted to deliver further doses.

3. The **Pro*dose*** handpiece is powered by an internal DC supply from the 115 v mains power supply unit. The HaloLite handpiece has an internal replaceable 9-volt battery.

4. The **Pro*dose*** air compressor system is able to supply longer aerosol pulses into long inhalation cycles, shortening treatment times for patients with these breathing patterns.

5. The **Pro*dose*** AAD System firmware utilizes a larger number of data points to compensate for inhalation airflows compared to HaloLite.

There are no other differences between the intended device and the predicate device, which would be significant to patient safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Profile Therapeutics PLC
C/O Mr. Paul Dryden
Promedic Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501

Re: K030747
Trade/Device Name: Prodose AAD System
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 24, 2004
Received: March 25, 2004

Dear Mr. Dryden:

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) 594-5613. 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

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Section 2a	(Revised) Indications for Use

510(k) Number: K030747 (To be assigned)

Device Name: **Prodose** AAD System

Indications for Use: A jet nebulizer system designed to aerosolize commonly prescribed liquid medication (except pentamidine) for inhalation by the patient in the home care, nursing home, sub-acute institutions or hospital environment.

Prescription Use X (Per CFR 801.109) **or** **Over-the-counter use __**

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K030747