**Non-Confidential Summary of Safety and Effectiveness**



26-Apr-07

APR 26 2007

PARI Innovative Manufacturers, Inc.
2943 Oak Lake Blvd. Tel – (804) 253-7274
Midlothian, VA 23112 Fax – (804) 639-7244

**Official Contact:** Mike Judge - RA

**Proprietary or Trade Name:** Hyper Sal

**Common/Usual Name:** Saline solution

**Classification Name:** CAF – Nebulizer (Direct Patient Interface)

**Device:** Inhaled saline solutions – 3.5%, 6% and 7%

**Predicate Devices:** DEY Laboratories – K972778

**Device Description:**

The proposed inhaled saline solutions are in 3.5%, 6% and 7% concentrations. They are packaged sterile in 4 ml vials for use as indicated.

**Indications for Use:**

| | |
|---|---|
| Indicated Use -- | Used in conjunction with a nebulizer for induction of sputum production where specimen collection is indicated.. |
| Patient Population -- | Any patient population |
| Environment of Use -- | Hospital, sub-acute care or home |
| Contraindications -- | None |

**Non-Confidential Summary of Safety and Effectiveness**



26-Apr-07

**Device Attributes:**

| Attributes | |
|---|---|
| Intended use | Used in conjunction with a nebulizer for induction of sputum production where specimen collection is indicated. |
| Environments of use | Hospital, sub-acute care or home |
| Patient Population | Any |
| Contraindications | None |
| Prescription | Yes |
| Design | |
| | USP sodium chloride solutions of 3.5%, 6% and 7% |
| Performance | |
| | None applicable<br>USP monograph |

**Differences between Other Legally Marketed Predicate Devices**

The proposed inhale saline solutions are viewed as substantially equivalent to the following predicate device – DEY K972778.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pari Innovative Manufacturers, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court #102
Bonita Springs, Florida 34134

APR 26 2007

Re: K070498
Trade/Device Name: Inhaled Saline Solutions 3.5%, 6%, and 7%
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 14, 2007
Received: February 20, 2007

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.

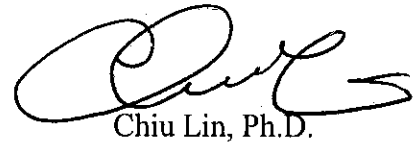
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

# 4 Indications for Use Statement



**510(k) Number:** K070498 (To be assigned)

**Device Name:** Inhaled saline solutions 3.5%, 6%, and 7%

**Indications for Use:** Used in conjunction with a nebulizer for induction of sputum production where specimen collection is indicated.

**Prescription Use XX** (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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 of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K070498