JUN 2 4 2004

Tiara Medical Systems, Inc.
14414 Detroit Ave., Ste. 205
Lakewood, OH 44107

Attachment 2 – 510(k) Summary

Submitter Name:	Tiara Medical Systems, Inc.
Submitter Address :	14414 Detroit Ave. Ste. 205 Lakewood, OH 44107
Contact Person:	Geoffrey Sleeper
Phone Number:	(216) 521-1220
Fax Number:	(216) 521-1399
Date Prepared:	December 2003
Device Trade Name:	SNAPP Soft Nasal Accessory for Positive Pressure
Device Common Name:	Nasal Mask
Classification Name:	Ventilator, Noncontinuous (Respirator), 73BZD
Predicate devices:	Tiara Medical Systems Advantage Series, K012207, Breathing Technologies Nasal Aire, K990659, Innomed Technologies Nasal Aire II ™, K022465, Sensormedics Lyra Nasal Mask, K031883,
Reason for submission:	Not previously marketed in the USA

Device Description and Materials:
The Tiara Medical Systems SNAPP Soft Nasal Accessory for Positive Pressure is a nasal cannula with inserts intended to be used with positive airway pressure devices such as CPAP (Continuous Positive Airway Pressure). It provides a seal such that positive pressure from a positive pressure source is directed into the patient's nose. It is held in place with an adjustable headgear. It may be cleaned with mild soap and water. The cleaning process does not require disassembly.
The device consists of latex-free silicone air delivery tubes connecting a polycarbonate Wye adapter / swivel with a latex-free silicone soft, resilient nasal inserts which form a seal with the nostrils.
The device connects to a conventional air delivery hose between itself and the positive airway pressure source via a standard 22 mm polycarbonate fitting on the combination Wye adapter / swivel. The built in vent slots are molded into the underside of the nasal insert body to direct air away from the patient's face and chest, and eliminate the need for a separate exhalation device. The vent slots may be visually checked for obstruction prior to use.
The SNAPP Headgear is available in three sizes to fit a broad range of facial structures, and attaches to the SNAPP via slots molded into the nasal insert body.

Intended Use:
The Tiara Medical Systems SNAPP is intended to be used with continuous positive airway pressure devices (CPAP), operating at or above 3 cmH20 for the treatment of obstructive sleep apnea. The SNAPP is intended for single patient use and can be used in the home or in a hospital/institutional environment. The SNAPP is to be used on adult patients (>30Kg) for whom continuous positive airway pressure has been prescribed.

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):
The Tiara Medical Systems SNAPP Soft Nasal Accessory for Positive Pressure is substantially equivalent to the Tiara Medical Systems Advantage Series, K012207, the Breathing Technologies Nasal Aire, K990659,, the Innomed Technologies Nasal Aire II ™, K022465, and the Sensormedics Lyra Nasal Mask, K031883.

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the Tiara Medical Systems SNAPP Soft Nasal Accessory for Positive Pressure to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the Tiara Medical Systems SNAPP Soft Nasal Accessory for Positive Pressure and the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Geoffrey Sleeper
Regulatory Manager
Tiara Medical Systems, Incorporated
14414 Detroit Avenue, Suite 205
Lakewood, Ohio 44107

Re: K034053
Trade Name: Snapp
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 30, 2004
Received: May 4, 2004

Dear Mr. Sleeper:

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,

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

Additional Requested Information, K034053
Section 510(k) Notification, Amended Submission
TMS SNAPP **ATTACH 1A**

Tiara Medical Systems, Inc.
14414 Detroit Ave., Ste. 205
Lakewood, OH 44107

INDICATIONS FOR USE

[510(k)] Number: K034053

Device Name: Tiara Medical Systems SNAPP (Soft Nasal Accessory for Positive Pressure

Indications For Use:

The Tiara Medical Systems SNAPP is intended to be used with continuous positive airway pressure devices (CPAP), operating at or above 3 cmH20 for the treatment of obstructive sleep apnea. The SNAPP is intended for single patient use and can be used in the home or in a hospital/institutional environment. The SNAPP is to be used on adult patients (>30Kg) for whom continuous positive airway pressure has been prescribed.

Prescription Use ✓ 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: K034053