Additional Requested Information, K031935
Section 510(k) Notification, Amended Submission
TMS Advantage II™ ATTACH 040302-1

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

MAR - 3 2004

Attachment 1 – 510(k) Summary of Safety and Effectiveness
[As required by 21 CFR 807.92(c)]

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:	June 2003
Device Trade Name:	Advantage II
Device Common Name:	Nasal Mask
Classification Name:	Ventilator, Noncontinuous (Respirator), 73BZD
Predicate devices:	TMS Advantage Series, K012207, Sullivan AutoSet Nasal CPAP System (includes ResMed Protoge), K980721
Reason for submission:	Modification to design, labeling

Device Description:
The Tiara Medical Systems Advantage II™ Nasal Mask is an externally placed mask covering the nose of the patient. It provides a seal such that positive pressure from a positive pressure source is directed to 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 requires limited disassembly.
The mask consists of a molded polycarbonate shell with a soft, resilient silicone skin-contacting cushion seal which conforms to the patient's facial features. A silicone forehead cushion is available for added comfort.
The mask connects to a conventional air delivery hose between the mask and the positive airway pressure source via a low profile 22 mm polycarbonate vented elbow/swivel. The elbow/swivel attaches to the front of the mask with a polyethylene split "c" ring. The built in vent slots (2) are located on the swivel 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 Advantage II™ headgear is available in a variety of sizes to fit a broad range of facial structures, and attaches to the mask via slots contained within the shell.

Intended Use:
The Tiara Medical Systems Advantage II Nasal Mask 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 mask is intended for single patient use and can be used in the home or in a hospital/institutional environment. The mask 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 modified device has the following similarities to the previously cleared predicate devices:

- same intended use
- same operating principle
- same technology, same materials in contact with patient's skin
- same manufacturing process

Design verification tests were performed on the TMS Advantage II Nasal Mask as a result of risk analysis and product specifications. All tests were verified to meet acceptance criteria. Tiara Medical Systems has determined that the modifications have no impact on the safety and efficacy of the device. In summary, the device described in this submission is substantially equivalent to the predicate device, and complies with the applicable standards referenced in the "FDA Reviewer Guidance for Premarket Notifications," November 1993."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

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

Re: K031935
Trade Name: Advantage II Nasal Mask, Models TMS-2520 and TMS-2530
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 15, 2004
Received: January 16, 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

INDICATIONS FOR USE

[510(k)] Number: K031935

Device Name: Tiara Medical Systems Advantage II™ Nasal Mask

Indications For Use:

The Tiara Medical Systems Advantage II Nasal Mask 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 mask is intended for single patient use and can be used in the home or in a hospital/institutional environment. The mask is to be used on adult patients (>30Kg) for whom continuous positive airway pressure has been prescribed.

Prescription Use__✓__ (Part 21 CFR 801 Subpart D) AND/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 Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031935