JAN 19 2005

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, 2004
Device Trade Name:	Full Advantage
Device Common Name:	Nasal Mask
Classification Name:	Ventilator, Noncontinuous (Respirator), 73BZD
Predicate devices:	TMS Advantage II, K031935, Hans Rudolph 7600 Series Reusable Full -Face CPAP/NIPPV Mask, K020759, Respironics Spectrum 2 Reusable Full-Face Mask, K002465
Reason for submission:	This device has not been previously marketed in the USA.

Device Description:

The Tiara Medical Systems Full Advantage™ Nasal Mask is an externally placed mask covering the mouth and 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 Tiara Medical Systems Full Advantage™ Full Face Mask is an externally placed mask covering the nose and mouth of the patient. It provides a seal such that positive pressure from a positive pressure source is directed to the patient's nose and mouth when either or both are open. 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 multiple sized polycarbonate shell with a soft, resilient silicone skin-contacting cushion seal which conforms to the patient's facial features. A silicone forehead pad attaches to a polycarbonate frame and is adjustable to suit patient comfort.

The mask connects to a conventional air delivery hose between the mask and the positive airway pressure source via a standard 22 mm polycarbonate elbow/swivel/valve assembly. The elbow/swivel/valve assembly attaches to the front of the mask with a polyethylene split "c" clip.

The built in vent ports are located on the elbow/swivel/valve assembly to provide a continuous air leak to prevent rebreathing of deadspace CO2, direct air away from the patient's face and chest, and eliminate the need for a separate exhalation device. The vent ports also allow the patient to exhale normally and do not interfere with the other performance requirements of the device. The vent ports may be visually checked for obstruction prior to use. The elbow/swivel/valve assembly also includes a built in Anti-Asphyxia Valve which allows the patient to continue to breathe fresh air in the event of positive air pressure device failure or output deterioration, or delivery hose kinking/obstruction.

Intended Use:

The Tiara Medical Systems FULL ADVANTAGE™ Nasal Mask is intended to be used with positive airway pressure devices such as CPAP (Continuous Positive Airway Pressure), operating at or above 3 cmH2O for the treatment of adult obstructive sleep apnea. The mask is intended for single patient use and reuse in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):

The technological characteristics of the Tiara Medical Systems Full Advantage™ Full Face Mask are equivalent to the predicate devices listed above.

Tests performed on the Tiara Medical Systems Full Advantage™ Full Face Mask demonstrate substantial equivalence to tne predicate devices listed above.

Conclusion:

The Tiara Medical Systems Full Advantage™ Full Face Mask is substantially equivalent to the predicate devices in terms of safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

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

Re: K043382
Trade/Device Name: Tiara Medical Systems FULL ADVANTAGE™ Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 8, 2004
Received: December 9, 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.

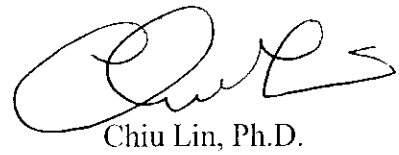
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

Attachment 1 – Statement of Indications for Use

510(k) Number: K043382

Device Name: Tiara Medical Systems FULL ADVANTAGE™ Full Face Mask

Intended Use / Indications for Use:

The Tiara Medical Systems FULL ADVANTAGE™ Full Face Mask is intended to be used with positive airway pressure devices such as CPAP (Continuous Positive Airway Pressure) for the treatment of adult obstructive sleep apnea.

Environment of Use / Patient Population:

The mask is intended for single patient use and re-use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use xx
(per 21 CFR 801.109)

OR

Over the Counter Use ___
Optional Format 1-2-96

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

510(k) Number: 1-1 K043382

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

Concurrence of CDRH, Office of Device Evaluation (ODE)