510(K) Summary

K122717

This summary of 510(K) is being submitted in accordance with the requirements of 21 CFR 807.92.

DEC 2 1 2012

1. Submitter's Identification:

Tiger Medical Products Ltd.
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China

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2. Device Name: Surgical Mask
Trade Name: Face Mask, Surgical Mask, Surgical Face Mask

3. Device Common Names: Mask, Surgical

4. Classification Name: Surgical Mask
Product Code: FXX

5. Device Description:
Surgical Mask is single use multi-layer mask with outer layer and inner layer (spunbond polypropylene) that sandwich a meltblown polypropylene filter material. There are 2 options for the surgical mask to be secured on user – via earloops or ties. Earloops are of urethane elastic fiber and latex-free; and ties are of spunbond polypropylene and also latex-free. The nose piece is a pliable white aluminum strip, covered by PP covering. All of the materials used in the construction of the Surgical Mask are being used in currently marketed devices.

6. Intended Use:
Surgical mask (with different trade names: Face Mask, Surgical Mask, Surgical Face Mask) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.

7. SE Comparison to Predicate Device:
K061716 - Prestige Ameritech Face Mask

Description		**Surgical mask**	**Predicate device** (K061716)	**SE discussion**
Materials	Inner layer	Spunbond polypropylene	Spunbond polypropylene or cellulose	Materials are similar to the predicate device
	Middle layer	Meltblown polypropylene	Meltblown polypropylene	
	Outer layer	Spunbond polypropylene	Spunbond polypropylene or medical grade tissue	
	Nosepiece	White Aluminum strip with PP covering	Aluminum strip	
	Headband	Urethane elastic fiber earloop or Spunbond polypropylene tie	Tie strip or elastic loop	
Intended use		Surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.	Prestige Ameritech Surgical Masks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.	Intended use is the same as the predicate device
Mask style		Flat pleated	Flat pleated	Mask style is the same as the predicate device
Design feature		Earloop or tie-on	Earloop or tie-on	Design feature is the same as the predicate device
Performance test result		**Surgical mask**	**Predicate device** (K061716)	**SE discussion**
Fluid resistance (ASTM 1862)		Fluid resistant	Fluid resistant	Fluid resistance performance is the same as the predicate device
PFE (ASTM F2299)		Average 99.54% at 0.1 micron	98.5% at 0.1 micron	PFE performance is similar to the predicate device
BFE		>99.9%	99.6%	BFE performance is

(ASTM F2101)			similar to the predicate device
Flammability Class (16CFR 1610)	1	1	Flammability is of the same class as the predicate device
Delta-P (MIL-M-36945C 4.4.1.1.1)	Average 3.38 mmH_2O/cm^2	2.6 mmH_2O/cm^2	Comfort scale of face mask is warm, while the predicate device is cool. The difference does not affect use.
Biocompatibility	No cytotoxicity (ISO 10993-5) No sensitization (ISO 10993-10) No irritation (ISO 10993-10)	Pass	Biocompatibility performance is the same as the predicate device

8. Conclusion:

Materials, intended use, mask style, design feature, and most performance test result of surgical mask is similar to or the same as the predicate device. The difference between surgical mask and the predicate device does not raise any question to safety and effectiveness. Surgical Mask is substantially equivalent to the predicate device.

Date: Aug.30, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Ms. Elaine Fong
Tiger Medical Products, Limited
Jaje Plaza, Suite 703
1717 North Sichuan Road
Shanghai, China 200080

Re: K122717
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: November 28, 2012
Received: November 28, 2012

Dear Ms. Fong:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

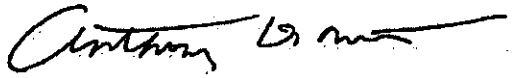
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122717

Device Name: Surgical Mask

Indications for Use:

The following surgical masks are intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and airborne particulates.

- -face mask (earloop)
- -face mask (tie-on)
- -surgical mask (earloop)
- -surgical mask (tie-on)
- -surgical face mask (earloop)
- -surgical face mask (tie-on)

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2012.12.20 14:00:15 -05'00'

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

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