510(k) SUMMARY

AUG 14 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990.

The assigned 510(k) number is: K061716

Submitted for:	Prestige Ameritech 7425 Airport Frwy. Fort Worth, TX. 76118 817 595-1131
Establishment Registration number:	3005022483
Contact Person:	Dan Reese, President 7425 Airport Frwy. Fort Worth, TX. 76118 817 595-1131
Date Prepared:	July 19, 2006
Proprietary Name:	Prestige Ameritech Face Mask (multiple labels); Prestige Ameritech Earloop Surgical Mask-Blue, Pink, Green, White, Yellow, Peach Prestige Ameritech Earloop Surgical Mask with splash shield-Blue Green, White, Peach Prestige Ameritech Earloop Surgical Mask Tissue-Blue, Pink, White, Yellow Prestige Ameritech Tie on Surgical Mask-Blue, Pink, Green, White, Peach Prestige Ameritech Tie on Surgical Mask with splash shield-Blue, Green, White, Peach
Common Name:	Surgical Face Mask
Classification Name:	Mask, Surgical
Classification Product Code:	FXX
Regulation Number:	878.4040
Predicate Devices:	Tucker and Associates Surgical Face Mask K022256 Hong Ya Non-Woven Products Co. Ltd. Surgical Face Mask K060776

K061716

Device Description: The Prestige Ameritech Surgical Mask device is composed of three layers of material flat folded and pleated to form the Mask. The inner layer is composed of cellulose or spunbonded polypropylene, the middle layer is a meltblown polypropylene filter material and the outer layer is a medical grade tissue or spunbonded polypropylene. Masks with splash shields have anti-fog plastic shields attached to masks. Masks are held in place on wearer with tie strips or latex free elastic loops and contain a malleable aluminum nosepiece strip. All of the materials used in this device are typical materials commonly used in the construction of Surgical Face Masks and are being used in current legally marketed devices.

Intended Use: The following 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.

Prestige Ameritech Earloop Surgical Mask-Blue, Pink, Green, White, Yellow, Peach
Prestige Ameritech Earloop Surgical Mask with splash shield-Blue Green, White, Peach
Prestige Ameritech Earloop Surgical Mask Tissue-Blue, Pink, White, Yellow
Prestige Ameritech Tie on Surgical Mask-Blue, Pink, Green, White, Peach
Prestige Ameritech Tie on Surgical Mask with splash shield-Blue, Green, White, Peach

Comparison To Predicate Devices:

Performance Characteristics	Test Method	Results K022256	Results K060776	Results Prestige Ameritech Device
Fluid Resistance	ASTM F1862	No Visual Penetration	Fluid Resistant	Fluid Resistant
Particulate Filtration Efficiency	ASTM F2299	2.0 microns	96.8% at 0.1 microns	98.5% at 0.1 Microns
Bacterial Filtration Efficiency	ASTM F2101	97.9%	99.9%	99.6%
Differential Pressure	Mil M36954C	1.8	2.34	2.6
Flammability Class	16CFR 1610	2	1	1

K061716

Discussion of Non-Clinical tests Performed for Determination of Substantial Equivalence:

1) Fluid Resistance-ASTM F1862
2) Particulate Filtration Efficiency-ASTM F2299
3) Bacterial Filtration Efficiency-ASTM F2101
4) Differential Pressure-MIL M36954C
5) Flammability Testing-16CFR 1610
6) Irritation and Sensitization-ISO 10993-10

Conclusions: The Prestige Ameritech Face Masks have the same intended use and technological characteristics as the predicate devices K022256 and K060776. Moreover, bench testing contained in this submission demonstrates that the technological characteristics do not raise any new question of safety or effectiveness. Therefore, the Prestige Face Mask (multiple labels) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2006

Mr. Dan Reese
President
Prestige Ameritech
7425 Airport Freeway
Fort Worth, Texas 76118

Re: K061716
Trade/Device Name: Prestige Ameritech Face Mask (Multiple Labels)
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: July 17, 2006
Received: July 20, 2006

Dear Mr. Reese:

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.

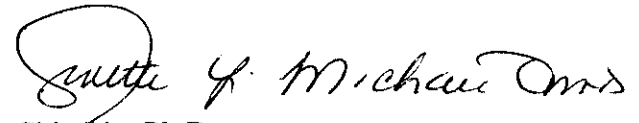
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

K061716

Indications for Use

510(k) Number (if known):

Device Name: Prestige Ameritech Face Mask (multiple labels)

Indications For Use:

The following 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.

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Prestige Ameritech Tie on Surgical Mask with splash shield-Blue, Green, White, Peach

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
ion of Anesthesiology, General Hospital,
ion Control, Dental Devices
Number: K061716