DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 7, 2016

Rodney Gregory
RA/QA Manager
Prestige Ameritech
7201 Iron Horse Blvd.
North Richland Hills, TX 76180
United States

Re: K160100
Trade/Device Name: Prestige Ameritech Pediatric/Child's Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: OXZ
Dated: August 30, 2016
Received: September 9, 2016

Dear Mr. Gregory,

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 contact 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. 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K160100

Device Name
Prestige Ameritech Pediatric/Child Face Mask

Indications for Use *(Describe)*
The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by the patient/child. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile. The Pediatric/Child Facemask is intended to be worn by the patient (ages 4-12) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. The mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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PRESTIGE AMERITECH

510(k) Summary

Date Summary was Prepared:	January 7, 2016
510(k) Submitter:	Rodney Gregory RA/QA Manager North Richland Hills, TX 76180 Phone: 817-427-2700 Fax: 817-886-2733 rodney@prestigeam.com
Device Trade Name:	Prestige Ameritech Pediatric/Child's Face Mask
Device Common Name:	Mask, Surgical
Device Product Codes and Classification Names:	OXZ, Class II Mask, Surgical (21 CFR 878.4040)
Predicate Devices:	K113340 Kimberly-Clark Pediatric/Child face mask(s)
Device Description:	The Prestige Ameritech Pediatric/Childs Face Mask is manufactured using ultrasonic bonding, composed of three layers of materials and pleated to form the mask. The inner layer is composed of nonwoven, the middle layer is meltblown polypropylene filter material, and the outer layer is cellulose. Decorative patterns are printed with colored inks. Masks are held in place on wearer with knitted polyester/spandex elastic earloop and contain a malleable aluminum nosepiece strip. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/Child's Face Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety of effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.
Intended Use:	The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by the patient/child. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile. The Pediatric/Child Facemask is intended to be worn by the patient (ages 4-12) to cover the nose and mouth to provide a barrier for the

respiratory tract for microorganisms and particulate materials. The mask is specifically for use with patients whose age or illness may prevent them from taking necessary precautions in situations where transfer of microorganisms, body fluids, and particulates can occur.

Biocompatibility: This is a surface-contacting, less than 24 hour duration device. The components that come into direct contact with the user are the inner material and earloops. The earloop and the manufacturing methods by which it is processed are identical to the predicate. The inner material has had MEM Elution, Repeated Patch Dermal Sensitization, and ISO Primary Skin Irritation, while the earloop material had MEM Elution and ISO Primary Skin Irritation biocompatibility tests performed.

Sterilization
And Shelf Life: The device is not proved sterile, has no proposed shelf life/expiration date, and is not a reprocessed single use device. The device is manufactured from non-woven materials that are not impacted by storage conditions or aging and thus does not have a shelf life.

Anthropometry: Based on an anthropometric study sample that is representative of the current US population in both gender and racial distribution, the Prestige Ameritech Child's/Pediatric face mask will provide adequate coverage to children between the ages of 4-12 years old, of weight between 24-153 pounds, and of height between 3'3" and 5'4".

Comparison to Predicate Device

Characteristic	K113340 (Predicate)	PRESTIGE AMERITECH DEVICE
Particulate Filtration Efficiency at 0.1 microns, ASTM F2299	98.5%	98%
Bacterial Filtration, ASTM F2101	99.6%	96.32%
Differential Pressure, Mil M36954C	2.6	1.74
Flammability Class, 16 CFR Part 1610	Class I	Class I
Biocompatibility	Tested under ISO 10993 Standard	Tested under ISO 10993 Standard
Intended Use	The Kimberly-Clark Pediatric/Child Facemask, is intended to be worn by the patient/child	The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by the patient/child

	(recommended ages 4-12) to provide protection for the respiratory tract. It is a single use, disposable device that is provided non-sterile. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.	(recommended ages 4-12) to provide protection for the respiratory tract. The Pediatric/Child's Face Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety of effectiveness. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.
Intended Use Sites	Healthcare setting	Healthcare setting
Product Code, Device Class, and Regulation	OXZ, Class II Mask, surgical (21 CFR 878.4040)	OXZ, Class II Mask, Surgical (21 CFR 878.4040)
Mask Construction and Technological Features	The Kimberly-Clark Pediatric/Child Facemask is a three layer mask, constructed of nonwoven polyester blends and polypropylene materials. Bindings are nonwoven polyester and earloops are knitted polyester/lycra. A malleable nosepiece is placed within the bindings for comfort and individualized fit around the wearer's nose. The Pediatric/Child Facemask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/Child Facemask is a single use, disposable device, provided non-sterile.	The Prestige Ameritech Pediatric/Childs Face Mask is manufactured using ultrasonic bonding, composed of three layers of materials and pleated to form the mask. The inner layer is composed of nonwoven, the middle layer is meltblown polypropylene filter material, and the outer layer is cellulose. Decorative patterns are printed with colored inks. Masks are held in place on wearer with knitted polyester/spandex elastic earloop and contain a malleable aluminum nosepiece strip. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/Child's Face Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety or

		effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.

Summary:

This device performs at the same fluid resistant level, equivalent particulate filtration efficiency, marginally lower bacterial filtration efficiency, a better differential pressure, and the same flammability class as the predicate device. The intended use is the same and that the subject Prestige Ameritech Device does not seek shelf life claim or provide storage conditions. These differences are not critical to the intended use of the device.

The mask construction is similar but has the following differences: the predicate device claims lycra in their earloops which is the same material as the Prestige Ameritech device's spandex in their ear loops; the Prestige Ameritech device has a cellulose outer facing instead of a polyester or polypropylene material. The Prestige Ameritech device also states the use of flexo-printed inks and that the device is not made with natural rubber latex.

Technological Characteristics and Substantial Equivalence: The Prestige Ameritech Pediatric/Child face mask has the same intended use and principles of operation as the predicate device. Based on the intended use, technological characteristics, and performance data, the subject device is substantially equivalent and is as safe and as effective as the legally marketed predicate device.

Summary of Testing:

The Prestige Ameritech Pediatric/Child face mask has been tested Under the following standards

Standard	Title
Mil – M369454C	Military Specification: Surgical Mask, disposable 1992
ASTM F2101-07	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol, Staphylococcus Aureus
PSC CS-191-53	Flammability Test Method (16 CFR 1610) for Flammability of Clothing Textiles
ASTM F2299	Standard Test Method for Evaluating the Initial Efficiency of Materials Used in Medical Masks to Penetration of Particulates Using Latex Spheres

CPSC-CH-E1002-08	Total Lead Content Analysis
CPSC-CH-C1001-09.3	Phthalate Analysis DEHP, DBP, BBP, DINP, DIDP, DnOP, and DnHP
ISO 10993	Standards for evaluating the biocompatibility of a medical device
EN 71-3	Safety of Toys – Migration of certain 19 elements

All results of testing met acceptance criteria.