PRESTIGE AMERITECH

510(k) Summary K102092

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

Submitted for: Prestige Ameritech
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OCT 6 2010

Establishment Registration number: 3005022483

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Date Submitted: September 21, 2010

Proprietary Name: Pro Gear N95 Particulate Filter Respirator and Surgical Mask

Common Name: N95 Surgical Respirator

Classification Name: Respirator and Surgical Mask

Classification Product Code: MSH

Regulation Number: 878.4040

Predicate Devices: Tecnol Medical Products, Inc. PFR95 Particulate Filter Respirator And Surgical Mask Regular Size K974068

Device Description: The Prestige Ameritech N95 Particulate Filter Respirator & Surgical mask is manufactured using ultrasonic bonding, composed of four layers of materials pouched and pleated to form the Mask. The inner layer is composed of nonwoven, the two middle layers is meltblown polypropylene filter material and the outer layer is spunbond polypropylene. Masks are held in place on wearer with latex free elastic headband and contain a malleable aluminum nosepiece strip. All of the materials used in this device are typical materials commonly used in the construction of Respirator and Surgical Masks and are being used in current legally marketed devices.

Intended Use: The Prestige Ameritech N95 Respirator and Surgical Mask RP88020 is a single use non-sterile disposable device 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.

Performance Data: **Fluid Resistance:** Subject device samples met the ASTM F1862 fluid resistance requirements @160 mmHg.
Particulate Filtration Efficiency: Subject device samples met the ASTM F2299 PFE requirements at 0.1 microns.
Bacterial Filtration Efficiency: Subject device samples met the ASTM F2101 BFE requirements.
Differential Pressure: Subject device samples met the Mil M36954C Delta P requirements.
Flammability Class: Subject device samples met the 16CFR 1610 Flammability Class 1 requirements.
Biocompatibility: Subject device samples met the requirements of ISO-10993-10-2002, "Biological Evaluation of Medical Devices"
Sodium Chloride (NaCl): Subject device samples met the NIOSH required sodium chloride test at ≤ 5% Penetration.
Inhalation Resistance: Subject device samples met the requirements of NIOSH inhalation resistance test which shall not exceed 35 mmH_2O.
Exhalation Resistance: Subject device samples met the requirements of NIOSH exhalation resistance test which shall not exceed 25 mmH_2O.

DEVICE AND PREDICATE DEVICE COMPARISON

DESCRIPTION	**PRESTIGE AMERITECH DEVICE**	**K974068**
MATERIALS; INNER	BICOMPONENT NONWOVEN	BICOMPONENT NONWOVEN
MATERIALS; MIDDLE 2 LAYERS	MELTBLOWN POLYPROPYLENE	MELTBLOWN POLYPROPYLENE
MATERIALS; OUTER	SPUNBOND POLYPROPYLENE	SPUNBOND POLYPROPYLENE
NOSEPIECE WIRE	MALLEABLE ALUMINUM	MALLEABLE ALUMINUM
SPECIFICATION	4 PLY FILTER BODY	4 PLY FILTER BODY
MASK STYLE	POUCH	POUCH
MASK DESIGN	HEADBAND	HEADBAND
MANUFACTURING METHOD	ULTRASONIC BONDING	ULTRASONIC BONDING

Substantial Equivalence Conclusion: The Prestige Ameritech N95 Particulate Filter Respirator and Surgical Mask have the same intended use and technological characteristics as the predicate device K974068. When compared with data available and/or claims made on the predicate device, demonstrate that the technological characteristics do not raise any new question of safety or effectiveness. Therefore, the Prestige Ameritech N95 Particulate Filter Respirator & Surgical Mask is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Barbara McCarty
Regulatory Affairs/ Quality Assurance Manager
Prestige Ameritech
7201 Iron Horse Boulevard
North Richland Hills, Texas 76180

OCT 6 2010

Re: K102092
Trade/Device Name: RP88020 – Pro Gear N95 Particulate Filter Respirator and Surgical Mask, Regular Size
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: July 26, 2010
Received: July 27, 2010

Dear Ms. McCarty:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K102092

Device Name: RP88020 - Pro Gear N95 Particulate Filter Respirator and Surgical Mask, Regular Size

Indications For Use:

The Prestige Ameritech N95 Respirator and Surgical Mask RP88020 is a single use non-sterile disposable device 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.

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 DCRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wills

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

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