K070782

5. 510(k) Summary

Submitter/Contact Person	Richard O. Wood The **Wood Burditt** Group FDA Regulatory Counseling 1025 W. Everett Rd., Suite 100 Lake Forest, IL 60045 (847) 234-7500 x 203 rowood@woodburditt.com (847) 574-0728 (fax) APR 11 2007
Applicant	Survivair Respirators LLC 3001 S. Susan St. Santa Ana, CA 92704
Manufacturer	Bacou Dalloz Plaintel (SAS) Gare 22940 Plaintel, France
Device Name	Willson® ONE-Fit™ Flat-Fold™ Healthcare Particulate Respirator and Surgical Masks, Models HC-NB095F and HC-NB295F
Common Name	Surgical N95 NIOSH-certified Respirator
Classification	Class II Procode MSH ✓ 21 C.F.R. §878.4040
Identification of Predicates and Summary of Substantial Equivalence	The Willson® ONE-Fit™ Flat-Fold masks are substantially equivalent to Survivair's own and recently cleared Willson® ONE-Fit™ HC-NB095 Cup-style Healthcare Particle Respirator and Surgical Mask (K070139). The Flat-Fold masks have been performance tested in an identical manner to the predicate, and passed standardized tests for fluid resistance, filter efficiency, bacterial filtration efficiency, flammability and breathing resistance. The materials used in the mask are virtually identical to the ones used on the cited predicate, and were also determined to be biocompatible by cytotoxicity, sensitization and skin irritation testing.
Device Description	The Willson ONE-Fit Flat-Fold Healthcare Particulate Respirator and Surgical Masks are flat-fold style particulate respirator and surgical masks. The only difference between the two models is the number of straps; one has a single strap, the other a double strap. The inner layer of the mask is constructed of spunbonded polypropylene, the middle layer is a filtration layer made of melt blown polypropylene and the outer layer is a covering of spunbonded polypropylene. The two halves that comprise the flat-fold facepiece are ultrasonically sealed together. The elastic head strap(s) is/are sandwiched between the upper and

	lower halves and is/are ultrasonically welded into the corners of the mask. The perimeter edges of the mask that contact the wearer's face are also ultrasonically sealed to provide reinforcement of the edges. The Willson ONE-Fit Flat-Fold Healthcare Particulate Respirator and Surgical Masks are approved by NIOSH in accordance with 42 CFR 84 as N95 particulate respirators. NIOSH has issued approvals TC-84A-4372 (single strap) and TC-84A-4371 (dual strap).
Intended Use and Indications	The Willson® ONE-Fit™ Flat-Fold™ Healthcare Particulate Respirator and Surgical Masks (Models HC-NB095F and HC-NB295F) are NIOSH-approved N95 single use respirators intended for use by healthcare personnel during medical/surgical procedures to protect both the wearer and the patient by protecting the wearer against the spatter of blood and other potentially infectious materials and reducing the transfer of microorganisms and other airborne particulate matter. The Willson ONE-Fit Flat-Fold masks also meet the CDC guidelines for TB exposure control within healthcare facilities and are intended for use as an isolation mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Survivair Respirators, LLC
C/O Mr. Richard O. Wood
The Wood Burditt Group
1025 W. Everett Road
Lake Forest, Illinois 60045

APR 11 2007

Re: K070782
Trade/Device Name: Willson® ONE-Fit Flat-Fold™ Healthcare Particulate Respirator and Surgical Mask, HC-NB095F & HC-NB295F
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: April 3, 2007
Received: April 4, 2007

Dear Mr. Wood:

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.

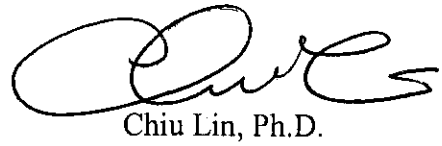
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

Print Form

Indications for Use

510(k) Number (if known): K070782

Device Name: Willson® ONE-Fit™ Flat-Fold™ Healthcare Particulate Respirator and Surgical Masks, HC-NB095F & HC-NB295F

Indications For Use:

The Willson® ONE-Fit™ Flat-Fold™ Healthcare Particulate Respirator and Surgical Masks (HC-NB095F & HC-NB295F) are NIOSH-approved N95 single use respirators intended for use by healthcare personnel during medical/surgical procedures to protect both the wearer and the patient by protecting the wearer against the spatter of blood and other potentially infectious materials and reducing the transfer of microorganisms and other airborne particulate matter.
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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N. Murphy MD

...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices

510(k) Number K070782