SHUENN BAO SHING CO., LTD.
No. 90,HSIN KUNG 6 RD., TIEN CHUNG CHEN,CHANG HWA HSIEN,
Taiwan, ROC
Tel: 886-4-875-6141 Fax: 886-4-875-6145
E-mail:shuennba@ms17.hinet.net http://www.aeropro.com.tw

" 510(k) SUMMARY "

JAN - 8 2008

The assigned 510(k) number is : K 072067

Submitter's Name: *SHUENN BAO SHING CORPORATION*

No. 90, Hsin Kung 6 Rd., Tien Chung Chen, Chang Hua Hsien, 52046, Taiwan, R.O.C.

Date summary prepared: July 20, 2007

Device Name:

- Classification name: *Respirator, Surgical*
- Classification number: *MSH, Class II*
- *Regulation Number*: *878.4040*
- Proprietary name: *N95 Surgical Respirator, Type: AP0018, AP0028*
- Common name of device: *Surgical Respirator*
- Predicate Device: *Surgical N95 Respirator, K041855*
- Official Correspondent: *Dr. Jen, Ke-Min*

  E-mail: ceirs.jen@msa.hint.net (Tel) 886-3-5208829; (Fax) 886-3-5209783

  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC

Description of the device:

SHUENN BAO SHING Corp. N95 Surgical Respirator AP0018 and AP0028 are flat pleated 3-ply masks with a center layer of polypropylene meltblown material by inner and outer layers of nonwoven material. The mask has 2 braided synthetic elastic headbands and a flexible wire tie nosepiece that allows the respirator to form to the bridge of the wearer's nose. No fiberglass media is used in this product.

Labels/Labeling:

This device will be marked to medical device suppliers, Dentist and Doctor Officers, clinics, Emergency Response Professionals, Hospitals and other healthcare professional for the Intended Use purpose below:

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Intended Use:

The N95 Surgical Respirator AP0018 and AP0028 are intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Comparison to Predicate Devices:

SHUENN BAO SHING Corporation N95 Surgical Respirator AP0018 and AP0028 are substantially equivalent is safety and effectiveness to the predicate device:

AEARO Company, K041855, Pleats Plus N95 Respirator 1050 and 1050S

for Reference: FXX, 878.4040, Class II

1) SHUENN BAO SHING Surgical Mask, K990719

2)3M Surgical Mask, K955382

Manufacturer	Shuenn Bao Shing Corporation (New Device)	Aearo Company (Predicate Device)
Device	AP0028 N95 Surgical Respirator	Pleats Plus N95 Respirator 1050 and 1050S
510(k) Number	TBA	K041855
Product Code	MSH, 878.4040	SAME
Device Description	1. N95 Class particulate respirator 2. Multi-Layer Filtering media (White spunbond polypropylene, Meltblown polypropylene) 3. Plastic Nose Wire- with Aluminum 4. Transparent PU headband 5. Dimensions: 24.5x8.5x8.7 cm 6. Flat pleated mask 7. Dual elastic head strap	1. N95 Class particulate respirator 2. Multi-Layer Filtering media (White spunbond polypropylene, Meltblown polypropylene) 3. Tie wire nose piece 4. White Elastic headband 5. Dimensions: 1) Small (13.5" circumference) 2) Large (15.5" circumference) 6. Flat pleated mask 7. Dual elastic head strap
NIOSH Approval Number	TC-84A-4175	TC-84A-2630
Regulatory Class	Class II (ASTM2100-04 Low Barrier)	SAME

AERO PRO
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Manufacturer	Shuenn Bao Shing Corporation (New Device)	3M (Predicate Device)--for reference
Device	AP0018 N95 Surgical Respirator	Model 1860 Health Care Respirator
510(k) Number	TBA	K955382
Product Code	MSH, 878.4040	FXX, 878.4040
Device Description	1. N95 Class particulate respirator 2. Multi-Layer Filtering media 3. Wire nose clip 4. Foam nose piece inside mask 5. Yellow elastic headband 6. White colored 7. Molded cup mask 8. Protruded wings prevent punching staple holes on the mask.	1. N95 Class particulate respirator 2. Multi-Layer Filtering media 3. Fluid resistant barrier 4. Wire nose clip 5. Foam nose piece inside mask 6. White elastic headband 7. Blue colored 8. Molded cup mask
NIOSH Approval Number	TC-84A-4049	TC-84A-006
Regulatory Class	Class II (ASTM2100-04 Low Barrier)	SAME

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

I. NIOSH, Exhalation Resistance Test 84.180
II. NIOSH, Inhalation Resistance Test 84.180
III. NIOSH, Sodium Chloride (NaCl)--N95 84.181
IV. Flammability, complied with16 CFR 1610, class I
V. Biocompatibility per ISO 10993

It was our conclusion that performance testing met all relevant requirements of the aforementioned test standard.

Discussion of Clinical Tests Performed:

Not Applicable

Conclusions:

SHUENN BAO SHING Corp., Surgical Respirator, type: AP0018 and AP0028, has the same intended use and technological characteristics as the predicated devices (K041855). Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new question of safety or effectiveness. SHUENN BAO SHING Surgical Respirator type AP0018 and AP0028 are substantially equivalent to the predicated device.

Thus the new device is substantially equivalent to the predicate devices.

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6. DEVICE DESCRIPTION

6.1 Vision Appearance

Product Picture :

We present the N95 Surgical Respirator, type: AP0018 and AP0028, appearance as the following pages.

Note: Relevant specification per Class II (ASTM2100-04 Low Barrier).

Product Description :

- SHUENN BAO SHING Corp. N95 Surgical Respirator AP0018 and AP0028 are flat pleated 3-ply masks with a center layer of polypropylene meltblown material by inner and outer layers of nonwoven material. The mask has 2 braided synthetic elastic headbands and a flexible wire tie nosepiece that allows the respirator to form to the bridge of the wearer's nose. No fiberglass media is used in this product.
- Non-Sterilized.
- For single use.

Product Directions :

Please refer to the Instruction as the following pages.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

Shuenn Bao Shing Corporation
C/O Dr. Ke-Min Jen
Official Correspondent
ROC Chinese-European Industrial Research Society
No. 58, Fu Chiun Street
Hsin Chu City
CHINA (TAIWAN) 30067

Re: K072067
Trade/Device Name: N95 Surgical Respirators, Type: AP0018, AP0028
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: December 22, 2007
Received: December 31, 2007

Dear Dr. Jen:

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

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Indications for Use

510 (K) Number (If Known): K072067

Device Name: *N95 Surgical Respirator, Type: AP0018, AP0028*

Indications for Use:

The N95 Surgical Respirator AP0018 and AP0028 are intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K072067