K080827

Handan Hengyong Protective &Clean Products Co.,Ltd
1-1 1201, 455 Gongnong Road, Shijiazhuang, Hebei, P.R.China
Tel: 86-311-83032925 Fax: 86-311-83995076

APR - 4 2008

510(k) Summary

This summary of 510K safety and effectiveness information is being submitted in accrodance with the requirements of 21 CFR 807.92.

The assigned 510K number is K080827

1. Submitter's Identification:

Handan Hengyong Protective & Clean Products Co.,Ltd
1-1-1201,455 Gongnong Road, Shijiazhuang,
Hebei Province, P.R.China

Contact:
Maggie Zhong
Tel:+86-21-33907930
Fax:+86-21-33907932
Mail: maggie-zhong2001@vip.sina.com

Date of Summary: April 2, 2008

2. Device Name:
Handan N95 Particulate Respirators and Surgical Masks, HY8510 & HY9810

3. Classification Name: Surgical N95 Mask

4.. Device Description

Handan HY8510 N95 particulate respirators and surgical mask is constructed from a polypropylene spunbond used in the inner and outer cover. The polypropylene melt blown filter media and polyester filter fabric are layered between the inner and outer cover. The head strap is made of polyester elastic(for single head strap) which is circled to the mask. The inside nosepiece is a PU foam.

Handan HY9810 N95 particulate respirators and surgical mask is constructed from a polypropylene spunbond used in the outer cover, polyester filter fabric used in the inner cover. The polypropylene melt blown filter media is layered between the inner and out cover. The head straps are made of polyester elastic(for double headband) which is welded to the mask. The inside nosepiece is a PU foam.

Both items are no—sterilized and only for single use.

5. Intended Use:

Handan type N95 respirators are intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates. These would include use as procedure mask, isolation mask or dental face mask.

6. Comparison to Predicate Devices

Handan Hengyong Protective &Clean Products Co.,Ltd
1-1 1201, 455 Gongnong Road, Shijiazhuang, Hebei, P.R.China
Tel: 86-311-83032925 Fax: 86-311-83995076

Handan N95 Particulate Respirators and Surgical Masks, HY8510 & HY9810 are substantially equivalent is safety and effectiveness to the predicate device.

Aearo Company-- K041855 Pleated plus 1050 and 1050S

Gerson Isolair Compay – k960778 APR Type N95 model 2735

for reference: FXX, 878, 4040. Class II

Manufacturer	Handan Hengyong Protective & Clean Products Co.,Ltd	Aearo Company Predicate device-for reference
Device	HY8510 N95 Surgical Mask (New device)	Pleated plus 1050 and 1050S
510K Number	K080827	K041855
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polypropylene spundbond, polypropylene, meltblown, polyester, polypropylene) 3. Plastic nose wire with steel 4. White elastic headband 5. Dimension 15.5" circumference 6. Flat pleated mask 7. Single elastic head strap	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (White spundbond polypropylene, meltblown polypropylene) 3. Tie wire nose piece 4. White elastic headband 5. Dimension Small (13.5" circumference) Large(15.5" circumference) 6. Flat pleated mask 7. Dual elastic head strap
NIOSH certification#	TC-84A-4276	TC-84A-2630

Manufacturer	Handan Hengyong Protective & Clean Products Co.,Ltd	Gerson Isolair APR Company Predicate device-for reference
Device	HY9810 N95 Surgical Mask (New device)	N95 model 2735
510K Number	K080827	K960778
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polyester, polypropylene meltblown, polypropylene) 3. Plastic nose wire with steel 4. White elastic headband 5. Dimension 15.75" circumference 6. Molded Cup 7. Dual elastic head strap	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (White nonwoven polyester meltblown polypropylene) 3. Plastic nose wire 4. Yellow elastic, latex free 5. Dimension Small (13.75" circumference) 6. Molded Cup 7. Dual elastic head strap
NIOSH certification#	TC-84A-4521	TC-84A-160

Handan Hengyong Protective &Clean Products Co.,Ltd
1-1 1201, 455 Gongnong Road, Shijiazhuang, Hebei, P.R.China
Tel: 86-311-83032925 Fax: 86-311-83995076

are as follows:

I. NIOSH, Exhalation of Resistance Test, 84.180

II. NIOSH Inhalation of Resistance Test, 84.180

III. NIOSH Sodium Chloride (Nacl) -N95 84.181

IV. Flammibility, Complied with 16 CFR 1610 Class I,

V. Biocompatibility per ISO 10993

It is our conclusion that performance testing meet all relevant requirements of the aforementioned test standard.

Disscussion of Clinical Tests Performed

Not Applicable

7. Conclusions

Handan N95 Particulate Respirators and Surgical Masks, HY8510 & HY9810 has the same intended use and technology characterisitics as the predicate devices (K041855, K960778). Moreover, the bench testing contained in this submission supplied domonstrate that the technological characterisistics do not raise any new question of safety or effectiveness.

Handan N95 Particulate Respirators and Surgical Masks, HY8510 & HY9810 are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Ms. Maggie Zhong
Consultant
Handan Hengyong Protective & Clean Products Company, Limited
1-1 1201, 455 Gongnong Road, Shijiazhuang
Hebei Province
P.R.CHINA

Re: K080827
Trade/Device Name: Handan N95 Particulate Respirators and Surgical Masks
HY8510, HY9810 Surgical N95 Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: March 15, 2008
Received: March 25, 2008

Dear Ms. Zhong:

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

Attachment A

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K080827

APPLICANT: Handan Hengyong Protective & Clean Products Co.,Ltd

DEVICE NAME: Handan N95 Particulate Respirators and Surgical Masks
HY8510, HY9810 Surgical N95 Respirator

INDICATION FOR USE:

The Handan N95 Particulate Respirators and Surgical Masks HY8510, HY9810 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. This includes use as a procedure mask, isolation mask or dental face mask. This device also meets CDC Guidelines for TB Exposure Control.

Prescription Use _____ AND/OR Over-The-Counter Use X
(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: K080827