Shanghai Dasheng Health Products Manufacture Co.,Ltd
No.228 Shihui Road, Zhongshan Street, Songjiang District, Shanghai
Tel: 86-21-57783126 Fax: 86-57784148

510(k) Summary

APR 27 2009

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 K090131

1. Submitter's Identification:

Shanghai Dasheng Health Products Manfuacture Co.,Ltd
No.228 Shihui Road, Zhongshan street, Songjiang District,
Shanghai, P.R.China

Contact:

Maggie Zhong
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Mail:

Date of Summary: Jan 11th, 2009

2. Device Name:

DS N95 Surgical Masks and flat surgical masks

3. Classification Name: Surgical N95 Mask and flat surgical mask

4.. Device Description

The DS DTC3M-1 N95 surgical mask is constructed from a polypropylene spunbond used in the outer layer. The non-woven PP micro is the filter media and the Terylene is layered as the inner. The head strap is made of natural rubber(for double head straps) which is stapled to the mask. The inside nosepiece is a soft sponge foam.

The DS DTC3B N95 surgical mask is constructed from a polypropylene spunbond used in the outer cover, a polypropylene spunbond used in the inner cover. The non-woven PP micro fiber and polypropylene melt blown filter media is layered between the inner and out cover. The head straps are made of woven elastic strap(for single headband) which is circule to the mask. The inside nosepiece is a EVA micro-aperture foam.

The flat surgical masks (colors: blue, green, pink, white, yellow, orange) are flat pleated by 3-ply masks with outer layer and inner layers (spunbonded polypropylene) that sanwich a meltbown non-woven PP micro fibre filter material; Ear-loops are made of spandex belt for free elastic loops. The nose piece for all DS Face Masks is malleable wire. Fog free masks have an anti-fog strip. Masks with splash visors have anti-fog treated plastic shield attached to masks,All of the material used in the construction of the DS Surgical Masks are being used in currently marketed devices (see predicate information).

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

5. Intended Use:

DS N95 surgical masks and flat surgical mask 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 procedure mask, isolation mask or dental face mask.

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6. Comparison to Predicate Devices

DS N95 surgical masks DTC3M-1. DTC3B and flat surgical masks color pink, blue, white, green, yellow, orange 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

Tucker & Associates company-K022256 Surgical face masks white, yellow, pink, blue and green

For reference: FXX, 878, 4040. Class II

Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Aearo Company Predicate device-for reference
Device	DTC3B N95 Surgical Mask (New device)	Pleated plus 1050 and 1050S
510K Number		K041855
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polypropylene spundbond, Non-woven PP Micro fiber meltblown, polypropylene, polypropylene) 3. Plastic nose wire 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-4336	TC-84A-2630

Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Gerson Isolair APR Company Predicate device-for reference
Device	DTC3M-1 N95 Surgical Mask (New device)	N95 model 2735
510K Number		K960778
Product code	MSH, 878.4040	SAME
Device Description	1. N95 Class Particuliar respirator 2. Multi-layer filteirng media (white polypropylene, non-woven PP micro fiber meltblown, Terylene) 3. Plastic nose wire 4. Natural rubber, latex free 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-4331	TC-84A-160

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Manufacturer	Shanghai Dasheng Health Products Manufacture Co.,Ltd	Tucker & Associates company for Predicate device-for reference
Device	Flat surgical mask white, yellow, pink, blue, orange, green(New device)	Surgical Face Mask colors; white, yellow, pink, blue and green
510K Number	_____	K022256
Product code	MSH, 878.4040	SAME
Device Description	1. Multi-layer filteirng media 2. Plastic nose wire 3. Flat pleated 4. loops or strips	1. Multi-layer filteirng media 2. Plastic nose wire 3. Flat pleated 4. loops or strip

Discussion of Non-clinical Test Performed for Determination of Substantial Equivalence 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

DS N95 Surgical Masks, DTC3M-1, DTC3B and flat surgical masks have the same intended use and technology characterisitics as the predicate devices (K041855, K960778, K022256). Moreover, the bench testing contained in this submission supplied domonstrate that the technological characterisistics do not raise any new question of safety or effectiveness.

DS N95 Surgical Masks, DTC3M-1, DTC3B and flat surgical masks are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2009

Ms. Maggie Zhong
Shanghai Dasheng Health Products
Number 228 Shihui Road Zhongshan Street
Songjiang District
Shanghai, CHINA

Re: K090131
Trade/Device Name: DS N95 Surgical Masks and Flat Surgical Masks for Single Use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH, FXX
Dated: April 8, 2009
Received: April 13, 2009

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting 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): K090131

APPLICANT: **Shanghai Dasheng Health Products Manufacture Co.,Ltd**

DEVICE NAME:

DS N95 Surgical Masks and Flat Surgical Masks for single use

DTC3M-1, DTC3B Surgical N95 Respirator

DS Surgical Ear- Loop Masks – Blue(FE3B), Pink(FE3P), Green(FE3G), Yellow(FE3Y), White(FE3W), Orange(FE3O)

DS Surgical Fog Free Ear-Loop Masks- Blue(FE3B-O), Pink(FE3P-O), Green(FE3G-O), White(FE3W-O), Orange(FE3O-O), Yellow(FE3Y-O),

DS Surgical Ear-Loop Masks with splash visor – Blue(FE3B-A), Pink(FE3P-A), Orange(FE3O-A), white(FE3W-A), Yellow(FE3Y-A), Green(FE3G-A)

DS Surgical Tie-On Masks – Blue(FT3B), Pink(FT3P), Green(FT3G), Yellow(FT3Y), White(FT3W), orange(FT3O)

DS Surgical Fog Free Tie-On Masks - Blue(FT3P-O), Pink(FT3P-O), Green(FT3G-O), Yellow(FT3Y-O), White(FT3W-O), Orange(FT3O-O)

DS Surgical Tie-On Masks with splash visor - Blue(FT3B-A), White(FT3W-A), Orange(FT3O-A), Yellow(FT3Y-A), Pink(FT3P-A), Green(FT3G-A)

INDICATION FOR USE:

The DS N95 Surgical Masks DTC3M-1/DTC3B, and flat surgical masks 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 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)

Concurrrence of CDRH, Office of Device Evaluation (ODE)

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

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