FEB 16 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K043199

1. Submitter's Identification:

Mr. Li Hua Zhu/General Manager
Hong Ya Non-Woven Products Co., Ltd.
Donggao Industry Zone
Zanhuang, Hebei Province
P.R. China

Official Correspondent and US Agent:
James Chu
Gloveco Inc.
590 W. Central Avenue, #D
Brea, CA 92821
Tel: 714-990-6888
Fax: 714-990-6478
Email: jameschu@glovecoinc.com

Date Summary Prepared: September 09, 2004

2. Classification Name:

Classified by FDA's General and Plastic Surgery Device panel as Class II, 21 CFR 878.4040, Surgical Apparel, 80FXX Mask, Surgical

3. Regulatory Reference:

21 CFR 878.4040

4. Name of the Device:

Hong Ya Non-Woven Products Co., Ltd.

Surgical Face Mask (Blue)

5. Predicate Device Information:

Tucker & Associates

Surgical Face Mask Colors: White, Yellow, Pink, Blue and Green (K022256)

6. **Device Description:**

Hong Ya Products Co., Ltd. Surgical Face Mask (Blue) is flat pleated 3-ply masks with an inner and outer layer (spunbonded polypropylene) that sandwich a meltblown polypropylene filter material, also with elastic loops and/or strip. The nosepiece for all Hong Ya Products Co., Ltd. Surgical Face Mask (Blue) is malleable aluminum wire. All the material used in the construction of the Hong Ya Products Co., Ltd. Surgical Face Mask (Blue) are being used in currently marked devices.

7. **Labels/Labeling:**

This device will be marked to medical device suppliers, Dentist and Doctor Offices, Clinics, Emergency Response Professionals, Hospitals and other healthcare professionals for the Intended Use purpose below.

8. **Intended Use:**

Surgical Face Mask is device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.

9. **Comparison to Predicate Devices:**

Hong Ya Products Co., Ltd. Surgical Face Mask (Blue) is substantially equivalent in safety and effectiveness to the Tucker & Associates Surgical Face Mask Colors: White, Yellow, Pink, Blue and Green.

Test	K022256	Hong Ya Surgical Face Mask (Blue)
Fluid Resistance	No visual Penetration	Fluid Resistant
Particulate Filtration Efficiency Performance (%)	2.0 microns	Average 98.8% at 0.1 micron
BFE (%)	97.9%	99.4%
Delta-P	1.8	1.6
Flammability Class	2	1

10. Discussion of Non-Clinical tests Performed for Determination of Substantial Equivalence are as follows:

I. Fluid Resistance (ASTM F1862-00a): Synthetic Blood Penetration Resistance Test

II. Filtration Efficiency: Bacterial Filtration Efficiency (BFE) Test (ASTM F2101-01) and Particulate Filtration Efficiency (Latex Particle Challenge) (ASTM F121589)

III. Differential Pressure (Delta P) Test (MIL M 36954C)

IV. Flammability Test (16 CFR 1610)

V. Biocompatibility per ISO 10933

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

11. Discussion of Clinical Tests Performed:

Not Applicable

12. Conclusions:

Hong Ya Non-Woven Products Co., Ltd. Surgical Face Mask (Blue) has the same intended use and technological characteristics as the predicated devices (K022256). Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. Hong Ya Non-Woven Products Co., Ltd. Surgical Face Mask (Blue) is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Hong Ya Non-Woven Products Company Limited
C/O Mr. James Chu
Official Correspondent
Gloveco, Incorporated
590 W. Central Avenue, #D
Brea, California 92821

Re: K043199
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: February 1, 2005
Received: February 2, 2005

Dear Mr. Chu:

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.

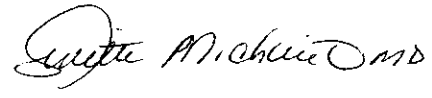
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K043199
APPLICANT: Hong Ya Non-Woven Products Co., Ltd.
DEVICE NAME: Surgical Face Mask (Blue)

INDICATIONS FOR USE:

Surgical Face Mask is device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K043199