JUN - 7 2004

ValuMax International Inc.

848 Hausman Road. Allentown PA 18104 Tel: 86-532-7937188 Fax: 86-532-7937288

C. 510(K) SUMMARY- Revised 5-6-04

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

The assigned 510K number is **K040333**

1. **Submitter & Foreign Manufacturer Identification**

   Qing Dao Tong Hui Clothing Co., Ltd.
   Xue-Chi Road, Hong Dao Industrial Park, Cheng Yang District,
   Qing Dao, Shan Dong, China 266114
   Tel: 86-532-7937188 Fax: 86-532-7937288
   Submitter's FDA Registration Number: 9616875

2. **US Agent & Applicant**

   ValuMax International Inc.
   848 Hausman Road
   Allentown PA 18104
   Tel: 610-336-0101 Fax: 610-336-0102

3. **Contact Person**

   Ms. Janet Jia, President
   ValuMax International Inc.
   848 Hausman Road
   Allentown PA 18104
   Tel: 610-336-0101 Fax: 610-336-0102

   Date of Summary: January 21, 2004

4. **Name of the Device:**

   - ValuMax® Surgical Ear Loop Masks – Blue, Pink, Green, Yellow, White, Peach
   - ValuMax® Surgical Fog Free Ear-Loop Masks– Blue, Pink, Green, White, Peach
   - ValuMax® Surgical Tie-On Masks – Blue, Pink, Green, Yellow, White, Peach
   - ValuMax® Surgical Fog Free Tie-On Masks – Blue, Pink, Green, Yellow, White
   - ValuMax® Surgical Ear-Loop Masks with splash visor – Blue, Pink, Peach
   - ValuMax® Surgical Tie-On Masks with splash visor – Blue, White, Peach

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C. 510(K) SUMMARY - Continued

5. **Classification Name: Mask, Surgical**

6. **Predicate Device Information:**
   K012602 – Crosstex Surgical Masks

7. **Device Description:**

ValuMax® Surgical Masks are pleated 3-ply masks. Inner and outer layers are made of either medical grade tissue or 100% spun-bond polypropylene. Middle layer is made of 100% meltblown polypropylene filter media. Ear-loops are made of soft latex free elastic loops. The nose piece for all ValuMax® Face Masks is malleable aluminum 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 ValuMax® Surgical Masks are being used in currently marketed devices (see predicate information).

8. **Intended Use – Revised on 5-27-2004:**

The following ValuMax® Surgical Masks are intended for use by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.

- ValuMax® Surgical Ear Loop Masks – Blue, Pink, Green, Yellow, White, Peach
- ValuMax® Surgical Fog Free Ear-Loop Masks– Blue, Pink, Green, White, Peach
- ValuMax® Surgical Tie-On Masks – Blue, Pink, Green, Yellow, White, Peach
- ValuMax® Surgical Fog Free Tie-On Masks – Blue, Pink, Green, Yellow, White
- ValuMax® Surgical Ear-Loop Masks with splash visor – Blue, Pink, Peach
- ValuMax® Surgical Tie-On Masks with splash visor – Blue, White, Peach

9. **Comparison to Predicate Devices:**

See previous attached documents

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C. 510(K) SUMMARY - Continued

10. Discussion of Non-Clinical Tests Performed for Dertermination of Substantial Equivalent are as Follows:

a. Bacterial Filtration Efficiency (BFE)
b. Pressure Differential (Delta P)
c. Latex Particle Challenge (PFE)
d. Flammability
e. Biocompatibility per ISO 10933
f. Fluid Resistant – Synthetic Blood Penetration Resistant Test

It is our conclusion that Performance Testing met all relevant requirements of the aforementioned test standards.

11. Discussion of Clinical Tests Performed:

Not Applicable

12. Conclusions:

The ValuMax® Surgical Masks have the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. The ValuMax® Surgical Masks 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

JUN - 7 2004

Ms. Janet Jia
President
ValuMax International, Incorporated
848 Hausman Road
Allentown, Pennsylvania 18104

Re: K040333
Trade/Device Name: Valumax Surgical Masks (Blue, Pink, Green, Yellow, White and Peach) with or without Visors, Ties and Earloops.
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: May 27, 2004
Received: June 1, 2004

Dear Ms. Jia:

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 (301) 594-4618. 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/dsma/dsmamain.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

Indications for Use

510(k) Number: K040333

Device Name:

ValuMax® Surgical Ear Loop Masks – Blue, Pink, Green, Yellow, White, Peach
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ValuMax® Surgical Fog Free Tie-On Masks – Blue, Pink, Green, Yellow, White
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ValuMax® Surgical Tie-On Masks with splash visors – Blue, White, Peach

Indications For Use:

ValuMax® Surgical Masks is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and 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 IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulvey

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

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