Winner

JUN 1 0 2003

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Winner Medical USA, Inc.

510K SUMMARY

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: K023755

1. Submitter's Identification:

   Winner Industries Co., LTD
   Winner Industrial Park,Bulong
   RD., Longhua, Shenzhen
   Shenzhen China 518109
   Telephone: 86-755-28138888
   Facsimile: 86-755-28134588

   U.S. Agent:
   Winner Medical USA, Inc.
   17815 Sky Park Circle, Suite A
   Irvine, California 92614
   Telephone: 800-996--9222
   Facsimile: 949-261-9007

   Contact Person: Ming Xie, Vice President

   Date of Summary: 11-3-02

2. Device Name:
   Winner Ear Loop Procedure Mask, Blue, Pink, White & Green
   Winner Tie-On Surgical Mask, Blue, Pink, White & Green
   Winner Ear Loop Procedure Mask with Shield, Blue, Pink, White & Green
   Winner Tie-On Surgical Mask with Shield, Blue, Pink, White & Green

3. Classification Name: Mask, Surgical

4. Predicate Device:

   a. K012602 - Crosstex Earloop & Tie Face Masks with/without splash visor.
   b. K001892 - White Knight Shield Mask

5. Intended Use: Medical facemask / shield are intended to be used 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 matter.

6. Device Description/ Comparison:
   These masks are pleated 3-ply masks with an inner and outer layer that sandwich a polypropylene filter material. On some masks a plastic shield with a non-fog coating is incorporated. The masks are identical to the predicate devices in design, materials used and performance in non-clinical testing. This testing included bacterial filtration efficiency (BFE), pressure differential (Delta P), flammability, ISO skin irritation and sensitization. This information has been included with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Winner Industries (Shenzhen) Company Limited
C/O Mr. Ming Xie
Winner Medical USA, Incorporated
17815 Sky Park Circle, Suite A
Irvine, California 92614

Re: K023755
Trade/Device Name: Winner Ear Loop Procedure Mask, Tie-On Surgical Mask & Ear-Loop White, Green, Blue, Pink with and without Face Shield
Regulation Number: 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Dated: May 13, 2003
Received: May 14, 2003

Dear Mr. Xie:

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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k Number (if Known): K023755

Device Name: Winner Medical Facemasks (various colors, with and without shields)

Indications for Use:

Winner Medical facemask / shield are intended to be used 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 matter.

Concurrence of CFRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

Olivia S. Lin

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

510(k) Number: K023755