Winner
WIN-WIN PARTNER

WINNER MEDICAL (USA), INC.

1900-H PROFORMA AVE. ONTARIO, CA. 91761 TEL: 909-947-9612 FAX: 909-947-9613

DEC 1 3 2005

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: K051242

1. Submitter's Identification:

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   Shenzhen China 518109
   Telephone: 86-755-28138888
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   U.S. Agent:
   Winner Medical USA, Inc.
   1900-H Proforma Ave.
   Ontario, California 92861
   Telephone: 909-947-9612
   Facsimile: 909-947-9613

   Contact Person: Ming Xie, Vice President

   Date of Summary: 5-6-05

2. Device Name: Winner® Self Seal Sterilization Pouch

3. Classification Name: Pack, Sterilization Wrapper, Bag and Accessories (21 CFR 880.6850).

4. Predicate Device:

   a. K993764 - Medipack® See-Through Self Seal Sterilization Pouch.
   b. K990567 - Global Healthcare Self-Sealing Sterilization Pouch.

K051242

5. Intended Use: Winner® Self Seal Sterilization Pouches are intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121°C for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

6. Device Description/ Comparison: These pouches are manufactured from a medical grade paper and plastic film that are heat sealed on three sides. The fourth side has an adhesive strip that is used to seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Winner® Self Seal Sterilization Pouch has the identical intended use and indication for use as the predicate devices, as well as, similar labeling. Substantial equivalent to the predicate device was established by testing the medical grade paper (pressure drop vs. flow and filtration efficiency) and film (thickness, tensile strength and elongation) from non-sterile, steam sterilized and ethylene oxide sterilized finished devices, as well as, performance of these finished devices (seal strength, package burst, dye migration, temperature distribution for steam and ethylene oxide sterilization, steam and ethylene oxide sterilization of biological indicators). 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

DEC 13 2005

Dr. Ming Xie
Vice President
Winner Medical USA, Incorporated
1900-H Proforma Avenue
Ontario, California 91761

Re: K051242
Trade/Device Name: Winner® Self Seal Sterilization Pouch
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: October 24, 2005
Received: October 31, 2005

Dear Dr. 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.

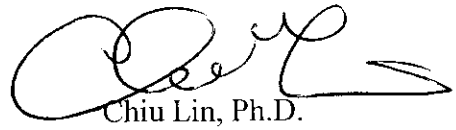
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K051242

Device Name: Winner® Self Seal Sterilization Pouch

Indications For Use:

Winner® Self Seal Sterilization Pouch is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121°C for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General Hospital, Infection Control, Dental Devices

510(k) K051242