K060859

JUL 18 2006

Compound W® Freeze Off™ Plantar Wart Removal System
Special 510k Summary

1. *Submitter's Name:* OraSure Technologies, Inc.
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820 ext. 5043
   Contact Person: Sue Sutton-Jones
   Date Prepared: 31 January 2006

2. *Device Name:*
   Proprietary Name: Compound W® Freeze Off™ Plantar Wart Removal System or other proprietary name
   Usual Name: OTC wart removal system
   Classification Name: Cryosurgical unit, accessories (21 CFR 878.4350), Product Code GEH.

3. *Device to Which Substantial Equivalence Is Claimed:*
   Compound W® Freeze Off™ Wart Removal System - K023487
   Wartner Wart Removal System, by Wartner Medical Products – K011708 (labeling only)

4. *Description of Device:*
   The Compound W® Freeze Off™ Plantar Wart Removal System is a cryosurgical system for the treatment of common warts and plantar warts. It consists of:
   - A canister filled with a liquid mixture of the compressed gases dimethyl ether, propane and isobutane
   - 12 Disposable Applicators
   - 1 Pumice Stone
   - 12 Foot Comfort Pads
   - 1 Reusable Activator that releases the cryogen into the applicator
   - An illustrated description of how to use the product with common and plantar warts

5. *Intended Use Statement:*
   The Compound W® Freeze Off™ Plantar Wart Removal System is indicated for over-the-counter treatment of common warts and plantar warts. There is no change to the intended use of this device.

6. *Comparison of Technological Characteristics to Predicate Devices:*
   The Compound W® Freeze Off™ Plantar Wart Removal System for over-the-counter treatment of common and plantar warts is substantially equivalent to both the Compound W® Freeze Off™ Wart Removal System by OraSure Technologies, Inc. and the Wartner Wart Removal System by Wartner USA b.v.. The primary predicate device (Compound W® Freeze Off™) uses the same applicator constructed of the same material. There is no change to the method of application to the wart.

This device is a portable cryosurgical system comprised of a canister containing cryogen and an applicator that is saturated with cryogen and then applied to the wart to be treated. Both devices are approved for the OTC treatment of common warts and plantar warts.

The labeling of the Compound W® Freeze Off™ Plantar Wart Removal System has been developed to ensure the consumer has adequate directions for use and for safety. Compound W® Freeze Off™ Wart Removal System labeling has been modified to provide adequate information for the consumer to use the pumice stone safely with plantar warts and to ensure that they contact their doctor if in any doubt, if stinging or aching persists after treatment, or if the wart does not improve after four treatments to seek physician advice. This direction is consistent with the existing warning and cautions regarding medical advice in our instructions for use.

The safety and warning statements for the OTC predicate device (Compound W® Freeze Off™ Wart Removal System - K023487) and for the labeling predicate device is essentially similar.

7. *Significant Changes or Modifications to the Device:*
There are no changes or modifications to the device.
   - Indications for use have not been changed or modified.
   - The safety and ease of use have been established in the 510k for this product - K023487.
   - The only modification to the Compound W® Freeze Off™ Wart Removal System is the addition of a small pumice stone that is optional for use in the treatment of plantar warts.
   - Instructions for use have been modified to include the use of the pumice stone in the treatment of plantar warts. This labeling change is consistent with the labeling of the predicate device, Wartner Wart Removal System, by Wartner Medical Products – K011708.

8. *Conclusion:*
Based on the information presented above, it is concluded that the proposed Compound W® Freeze Off™ Plantar Wart Removal System
is safe and effective for its intended use and is substantially equivalent to the primary predicate device. It is also substantially equivalent in intended use, safety, and labeling to the labeling predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

OraSure Technologies, Inc.
% Ms. Sue Sutton-Jones
Senior, VP, Regulatory Affairs & Quality
220 East First Street
Bethlehem, Pennsylvania 18015-1360

Re: K060859
Trade/Device Name: Compound W® Freeze Off™ Plantar Wart Removal System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: June 22, 2006
Received: June 23, 2006

Dear Ms. Sutton-Jones:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060859

Device Name: Compound W® Freeze Off™ Plantar Wart Removal System

Indications For Use: The Compound W® Freeze Off™ Plantar Wart Removal System is indicated for over-the-counter treatment of common and plantar warts.

Prescription Use _______ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MXM
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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