PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

K023487

MAR 2 0 2003

807.92 (a):

1. *Submitter's Name:* OraSure Technologies, Inc.
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: October 15, 2002

2. *Device Name:*
   Proprietary Name: Histofreezer® Wart Removal System or other proprietary name
   Usual Name: OTC wart removal system
   Classification Name: Cryosurgical unit, accessories

3. *Device to Which Substantial Equivalence Is Claimed:*
   Histofreezer® Device, by OraSure Technologies, Inc. (**Primary Predicate**) – K911420, K924114, K971392
   Wartner Wart Removal System, by Wartner Medical Products (**OTC claim**) – K011708
   Compound W Gel, by Medtech (**labeling only**)
   Clear Away Liquid, by Schering-Plough HealthCare Products, Inc. (**labeling only**)
   Clear Away One Step for Kids, by Schering-Plough HealthCare Products, Inc. (**labeling only**)
   Rite Aid Wart Liquid, by Rite Aid Corporation (**labeling only**)
   Suave Hairspray, by Helene Curtis (**flammability label only**)

4. *Description of Device:*
   The Histofreezer® Wart Removal System is a cryosurgical system for the treatment of warts. It consists of:
   - A canister filled with a liquid mixture of the compressed gases dimethyl ether, propane and isobutane
   - Custom applicators
   - An illustrated description of how to use the product

5. *Intended Use Statement:*
   The Histofreezer® Wart Removal System is indicated for over-the-counter treatment of common warts and plantar warts.

6. *Comparison of Technological Characteristics:*
   The Histofreezer® Wart Removal System for over-the-counter treatment of common and plantar warts is substantially equivalent to the Histofreezer® device for the same indications (for prescription use). Both devices are portable cryosurgical systems comprised of a canister containing cryogen and an applicator that is saturated with cryogen and then applied to the wart to be treated. The Histofreezer® Wart Removal System, however, is intended for OTC treatment of common warts and plantar warts.

The labeling of the Histofreezer® Wart Removal System has been developed to ensure the consumer has adequate directions for use and for safety. Histofreezer® labeling has also been developed to provide adequate information for the consumer to make a self diagnosis 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.

The safety and warning statements for the OTC predicate device (Wartner Wart Removal System) and for all of the labeling predicate devices is essentially similar.

7. *Conclusion:*
Based on the information presented above, it is concluded that the proposed Histofreezer® 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

APR 2 5 2003

R. Sam Niedbala, PH.D., BCFE
Orasure Technologies, Inc.
150 Webster Street
Bethlehem, Pennsylvania 18015-1389

Re: K023487
Trade/Device Name: Histofreezer® Wart Removal System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: February 5, 2003
Received: February 19, 2003

Dear Dr. Neidbala:

This letter corrects our substantially equivalent letter of March 20, 2003, regarding the intended use of the device mentioned above. The intended use for the device was over-the-counter; however, the indications for use form indicated prescription use.

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K023487

Device Name: Histofreezer® Wart Removal System or other proprietary name

Indications For Use: The Histofreezer® Wart Removal System is indicated for over-the-counter treatment of common and plantar warts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)

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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023487