K030838

JUN 2 7 2003

510(k) Summary

1. Submitter's Name, Address and Contact Person

Submitter
Wartner Medical Products
Ijsbaanpad 1a
1076 CV Amsterdam
The Netherlands

Telephone: 31 (0) 20 305 9100
Facsimile: 31 (0) 20 305 9109

Contact Person
Nancy Lum-Wilson
N. Wilson Consulting Inc.
65 Ava Crescent
Richmond Hill, Ontario
CANADA L4B 2X5

Telephone: 905-884-7855
Facsimile: 905-508-8599

Date Summary Prepared: January 17, 2003

2. Name of Device

WARTNER PRO®

3. Name of Predicate Device(s)

- Wartner® Wart Removal System for OTC use, by Wartner Medical Products **(Primary Predicate)**

- Histofreezer® Portable Cryosurgical Unit, by Orasure Technologies Inc. **(Labeling predicate)**
- Tinamed® Plantar Patch, by Stiefel laboratories, Inc. **(Labeling predicate)**
- Tinamed® Wart Remover indicated for common warts and plantar warts, by Stiefel laboratories, Inc. **(Labeling predicate)**
- Maximum Strength Wart-Off®, by Consumer Health Care Group Pfizer Inc, Dist. **(Labeling predicate)**
- DuoFilm® Salicylic Acid Wart Remover indicated for common warts and plantar warts, by Schering-Plough HealthCare Products, Inc. **(Labeling predicate)**
- Clear Away® System Plantar Wart Remover for Feet, by Schering-Plough HealthCare Products, Inc. **(Labeling predicate)**

4. Description of Device

WARTNER PRO® is a cryosurgical system for the treatment of warts. It consists of

- A canister filled with 125 ml of a liquid mixture of the compressed gases dimethyl ether and propane. This gas mixture does not harm the ozone layer, and has a four-year shelf life.
- 42 Foam applicators in three different sizes (6 mm, 7 mm, 8 mm)
- An applicator stick/key for holding a foam applicator which is required to dispense the liquid to the applicator, and is held by the person during treatment
- Information booklet

The pressurized canister is filled with dimethyl ether and propane, which acts as a cryogen. The key is fitted with a foam applicator, which is inserted into the safety valve opening in the canister. The valve releasing the cryogen can only be actuated when the key is in place and depressed. When the key is depressed it saturates the foam applicator with the cold cryogenic gases and lowers the temperature of the applicator to approximately -50°C. The foam applicator is then placed on the wart. The freezing kills the wart and the infected skin causing the wart to fall off within a few days.

5. Statement of Intended Use

WARTNER PRO® is intended for the treatment of common warts and plantar warts in adults and children over the age of 4. Common warts are recognized by the rough 'cauliflower-like' appearance of the surface. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern. The product is intended as an OTC device, which will be marketed to professionals, allied professionals, and semi-professionals.

6. Statement of Technological Characteristics of the Device

a) Laboratory Testing:

The average temperature of the applicator surface after saturation is -56.4° C.

A discussion of the testing methodology is included in the "Performance" section of this submission. Several lengths, sizes, and shapes of foam were tested to identify the optimum characteristics of liquid retention (minimal dripping) and versatile shape for treating various sizes of warts.

b) Biocompatibility:

The cryogen used in WARTNER PRO® is a mixture of dimethyl ether and propane, which is the exactly same as the cryogen used in the predicate device, Wartner® Wart Removal System for OTC use.

The material used to transfer the cold to the patient in both WARTNER PRO® and Wartner® Wart Removal System for OTC use is the same foam material. The foam is well characterized chemically and physically in the published literature.

c) Comparison to Predicate Device(s):

Application
WARTNER PRO® provides an applicator and key, which is removed from the tube of cryogen after saturation and can be easily manipulated to treat warts. Three sizes of applicators (6 mm, 7 mm, 8 mm) are included within the kit to treat warts of various sizes.

The Wartner® Wart Removal System OTC predicate device applicator is identical in shape. However, only the 8 mm size is included. The applicator key is identical.

Applicator Effectiveness Duration
The WARTNER PRO® foam applicator maintains a temperature of less than minus 50°C.

The Wartner® Wart Removal System OTC predicate device effectiveness is identical

Cryogen
WARTNER PRO® uses a cryogen composed of dimethyl ether and propane.

The Wartner® Wart Removal System OTC predicate device cryogen is identical.

Safety/Ease of Use:

The design of both WARTNER PRO® and Wartner® Wart Removal System OTC incorporate the use of a safety valve that cannot be actuated unless the foam applicator and applicator stick/key are in place and depressed.

Indications for Use:

WARTNER PRO® is indicated for the treatment of common warts and plantar warts in adults and children over the age of 4. It is intended as an OTC device and will be marketed to professionals, allied professionals and semi-professionals.

Wartner® Wart Removal System is indicated for the treatment of common warts in adults and children over the age of 4. It is marketed to the general public.

Labeling:

The labeling of WARTNER PRO® and Wartner® Wart Removal System have been developed to ensure the consumer and professional have adequate directions for use and for safety. The labeling also provides adequate information for self-diagnosis and ensures a doctor is contacted if there is any doubt, if stinging or aching persists after treatment or if the condition does not improve after three treatments. The labeling for WARTNER PRO® is virtually identical to that of Wartner® Wart Removal System for OTC use, except for the addition of the "plantar wart" indication and any reference to plantar warts.

The safety and warning statements for WARTNER PRO® and the primary predicate device (Wartner® Wart Removal System for OTC use) are identical except for any reference to plantar warts. The WARTNER PRO® safety and warning statements for the plantar wart indication have been developed using the other labeling predicates (Histofreezer®, Tinamed® Plantar Patch, Maximum Strength Wart-Off®, DuoFilm® Salicylic Acid Wart Remover indicated for common warts and plantar warts, Tinamed® Wart Remover indicated for common warts and plantar warts) to ensure that they are comparable.

7. Conclusion

Based on the information presented above it is concluded that the proposed WARTNER PRO® 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

JUN 27 2003

Wartner Medical Products
c/o Ms. Nancy Lum-Wilson
N. Wilson Consulting, Inc.
65 Ava Crescent
Richmond Hill, Ontario
Canada L4B 2X5

Re: K030838
Trade/Device Name: WARTNER PRO®
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: June 16, 2003
Received: June 18, 2003

Dear Ms. Lum-Wilson:

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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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

Wartner Medical Products
WARTNER PRO®

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K030838

Device Name: WARTNER PRO®

Indications for Use: **WARTNER PRO® is intended for the treatment of common warts 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) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030838