K011708

Wartner Medical Products
Wartner Wart Removal System

FEB 2 0 2002

Safety and Effectiveness Summary

1. Submitter's Name, Address and Contact Person

Submitter

Wartner Medical Products
Europark 20
4904 SX Oosterhout
Netherlands

Telephone: 00 31 162 437 268
Facsimile: 00 31 162 437 269

Contact Person

Nancy Lum-Wilson
N. Wilson Consulting Inc.
25 Bellini Ave.
Brampton, Ontario
L6T 3Z8 CANADA

Telephone: 905-794-3339
Facsimile: 905-794-0633

Date Summary Prepared: May 25, 2001

2. Name of Device

Wartner Wart Removal System

3. Name of Predicate Device(s)

Wartner Wart Removal System, by Wartner Medical Products **(Primary Predicate)**
Compound W Gel, by Medtech **(labeling only)**
Compound W Pads for Kids, by Medtech **(labeling only)**
Clear Away Gel, by Schering-Plough HealthCare Products, Inc., **(labeling only)**
Clear Away Liquid, 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

Wartner Wart Removal System is a cryosurgical system for the treatment of warts. It consists of

- A canister filled with 35 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.
- Ten foam applicators
- An applicator stick/key for holding a foam applicator, required to dispense the liquid to the applicator, and held by the person during treatment
- An illustrated description of how to use the product

5. Statement of Intended Use

Wartner Wart Removal System is intended for the over-the-counter treatment of common warts.

6. Statement of Technological Characteristics of the Device

a) Laboratory Testing:

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

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 is a mixture of dimethylether and propane, which is the same as cryogen used in the predicate device, Wartner Wart Removal System for prescription use.

The material used to transfer the cold to the patient in both Wartner Wart Removal System OTC and the predicate device is a foam material. The foam used in Wartner which has contact with the wart is S616 foam which is well characterized chemically and physically in the published literature.

c) Comparison to Predicate Device(s):

Application
Wartner for OTC use provides an applicator, which is removed from the tube of cryogen after saturation and can be easily manipulated to treat warts of various sizes.

The Wartner prescription use predicate device applicator is identical.

Applicator Effectiveness Duration
Wartner's foam applicator maintains a temperature of less than minus 50°C for up to five minutes.

The Wartner predicate device effectiveness is identical

Cryogen
Wartner uses a cryogen composed of dimethylether and propane.

The Wartner predicate device cryogen is identical.

Safety/Ease of Use:

Wartner's design incorporates the use of a safety valve that cannot be actuated unless the foam applicator and holder are in place. The Wartner prescription use predicate device has an identical safety valve.

Indications for Use:

Wartner Wart Removal System is indicated for OTC treatment of common warts. The predicate device, Wartner Wart Removal System for prescription use is indicated for the treatment of common warts by a physician.

Labeling:

The labeling of Wartner Wart Removal System has been developed to ensure the consumer has adequate directions for use and for safety. Wartner labeling has also been developed to provide adequate information for the consumer to make a self diagnosis and to ensure they contact their doctor if in any doubt, if stinging or aching persists after treatment or if the wart does not improve after three treatments.

The safety and warning statements for the primary predicate device (Wartner Wart Removal System for prescription use) and for all of the labeling predicate devices (Compound W Gel, Compound W pads, Clear Away Gel, Clear Away Liquid, Rite Aid Wart Liquid) is essentially similar. In addition, Wartner contains an essentially similar flammability statement to Suave Hairspray (Flammability label predicate), which uses an aluminum container and contains dimethyl ether and alcohol for use by the general public.

7. Conclusion

Based on the information presented above it is concluded that the proposed Wartner 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

FEB 2 0 2002

Wartner Medical Products
c/o Ms. Nancy Lum-Wilson
N. Wilson Consulting, Inc.
25 Bellini Avenue
Brampton, Ontario
L6T 3Z8 Canada

Re: K011708
Trade/Device Name: Wartner Wart Removal System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: January 18, 2002
Received: January 22, 2002

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K011708

Device Name: **Wartner Wart Removal System**

Indications for Use : **Wartner Wart Removal System is intended for the treatment of common warts.**

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

510(k) Number K011708

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ (Per 21 CFR 801.109) OR Over-the-Counter Use X (Optional Format 1-2-96)