

K101049

JUN 23 2011

Koninklijke Utermöhlen NV
Traditional 510(k)

Wart Freeze

Section B - 510(k) Summary

Manufacture Name:	Koninklijke Utermöhlen NV
Contact Name:	Foki van 't Zand
Postal Address:	De Overweg 1, 8471 ZA Wolvega
Phone Number:	+31 (0) 561-693310
Title:	Quality Control Manager
Date:	April 14, 2010

Device Proprietary Name:	Wart Freeze
Device Common or Usual Name:	OTC wart removal system
Classification Name:	Cryosurgical unit, accessories
Classification Code:	GEH
Regulation Number:	21 CFR 878.4350

Predicate Devices:

Substantial equivalence is claimed to the following devices.

Name of Device	Manufacturer	Predicate Comparison	510(k) Number
Wartner Wart Removal System	Wartner Medical Products	Intended Use, technology, materials	K011708
Wartner Wart Removal System	Wartner USA b.v	Intended Use, technology, materials	K032271
Dr. Scholl's Freeze Away Wart Remover	Schering-Plough HealthCare Products, Inc	Intended Use, technology, materials	K031697
Histofreezer Wart Removal System	OraSure Technologies, Inc	Intended Use, technology, materials	K023487
Acon 30 Second Reliable Digital Thermometer	ACON Laboratories, Inc	Labeling related to cleaning	K060173

Description of the Device

Wart Freeze is an over the counter cryosurgical product to remove common and plantar warts.

The device consists of the following:

- Pressurized canister with the cryogen liquid dimethyl ether (DME)
- a dose valve which expels a specific quantity of the cryogen onto the wart
- a polypropylene reusable applicator
- 70% alcohol disposable cleansing swabs
- Protective plasters (bandages)

Intended Use/Indications for Use

Wart Freeze is indicated for the removal of common and plantar. The wart remover product is intended to be used in adults and children 4 years of age and over.

Technological Characteristics

The subject and predicate devices are portable cryosurgical systems comprised of a canister containing cryogen and an applicator to apply the cryogen to the wart.

Pre-Clinical Testing

The following functionality tests on the finished product and/or components were performed:

1. Comparative testing between Wart Freeze and the predicate devices using a phantom skin test model.
2. Applicator temperature test to determine the degree of cold generated by the cryogen on the applicator.
3. Dose technique test to determine the dispensing freeze time between the two potential dose techniques. Subsequent testing was conducted to determine whether or not there was any difference in the effectiveness between the dose techniques.
4. The maximum allowable concentration of DME was determined

Biocompatibility testing was performed to determine the safety of the cryogen as well as the material used to manufacture the applicator. In addition, a safety test was conducted on the finished product to identify any potential chemical residuals including leachable or degradable components.

A label comprehension study was performed to ensure that the instructions for use as well as the package label were clear and understandable by the general public for the safe and effective use of the device.

It was concluded that the bench, biocompatibility and label comprehension studies support the safety and effectiveness of Wart Freeze.

Substantial Equivalence Discussion

The subject and predicate devices are similar in terms of application, safety and ease of use and indications for use.

Conclusion

Based on the information provided in this 510(k) premarket notification, Wart Freeze is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUN 23 2011

Koninklijke Utermohlen NV
% Canreg, Inc.
Shirley Furesz, Ph.D., RAC
Manager, Regulatory Affairs - Devices
4 Innovation Drive
Dundas, Ontario, Canada L9H 7P3

Re: K101049

Trade/Device Name: Wart Freeze
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 13, 2011
Received: June 14, 2011

Dear Dr. Furesz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

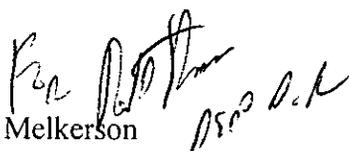
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section A - Indications for Use

510(k) Number: K101049

Device Name: Wart Freeze

Indication for Use: Wart Freeze is indicated for the removal of common and plantar warts.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 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 Sign-Off

Division of General, Restorative and Neurological Devices

510(k) _____

Neil R. Ogden for me
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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