YouMedical

Premarket Notification 510(k) Summary Wartie

Sub. N.: K140314
Version: 3.0
Date: 06-June-14

Premarket Notification 510(k) summary (As Required by 21 CFR 807.92)

JUN 12 2014

Submitter's Name: YouMedical BV,
Address: Rijnsburgstraat 9-11,
1059AT Amsterdam, The Netherlands.
Contact Person: Kathleen Johnson
Date Prepared: 06th June, 2014

Device Trade Name: Wartie®
Proprietary Name: Wartie® Wart Remover and other proprietary name
Common Name: OTC Wart Removal System
Classification Name : Cryosurgical unit, accessories
Classification Panel : General & Plastic Surgery
Classification Code : GEH
Regulation Number : 21 CFR 878.4350

Predicate Devices:
Substantial equivalence is claimed with the following devices:

Name of Device	**Manufacturer**	**Predicate Comparison**	**510(k) Number**
Wartner® Wart Removal System	Wartner US b.v	Intended use, technology, materials, label.	K032271
Dr. Scholl's® Freeze AwayTM Wart Remover	Schering-Plough Healthcare Products, Inc.	Intended use, technology, materials, label.	K031697
Histofreezer® Wart Removal System	OraSure Technologies, Inc.	Intended use, technology, materials, label.	K023487

Wart Freeze	Koninklijke Utermöhlen N.V.	Intended use, technology, materials.	K130599

Description of the Device:

The Wartie® Wart Remover is effective in the treatment of warts by providing an over the counter cryosurgery product (for the treatment of warts), to be used at home.

Wartie® Wart Remover consists of:

- A pressurized canister filled with 50ml of the compressed liquid gas dimethyl ether.
- A custom application unit used to administer the cold delivered by the cryogen to the wart.
- Instructions for use in which you can read about the product how it works, how to use the product to treat warts, warnings and limitations.

The Biological Safety Evaluation of the Wartie® Wart Remover assesses the chemical characterization of the product, reviews the literature data on safety aspects and assesses the need for biological safety testing according to ISO 10993. The biological safety evaluation has identified and discussed the materials coming into contact with the body during use. Special attention has been given to the nickel coating of the metal tip, which is in direct contact with the wart during application. The biological safety evaluation has shown that the levels of nickel dissociation of the product are within the applicable safety limits and safe for use as indicated. YouMedical BV has evaluated the total possible exposure of Wartie® Wart Remover considering the nature of the product and its evaluation and has established that the maximum possible exposure levels are well within the accepted limits. The biological safety evaluation has established the parameters of use of Wartie® Wart Remover and its equivalence to the predicate device.
Based on the chemical composition of contacting materials during treatment and their safety data, the short term contact during treatment, extremely low temperature of the tip during skin contact and the mode of action of Wartie® Wart Remover it can be concluded that the biological and performance safety risks of Wartie® Wart Remover for its intended use and application are low and therefore acceptable. Residual risks are identified and directly related to the mode of action (freezing) of the Wartie® Wart Remover and presence of nickel. The extent of residual risks are estimated lower or equal when compared to predicate products and therefore regarded acceptable. Information on the residual risks is provided in the information to the user.

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Wartie® Wart Remover technology involves freezing a wart (common and/or platar) using a very cold releasing liquid gas (cryogen) into a patented-pending applicator which, in turn become very cold and is able to freeze the skin. The freezing of the skin causes damage to the cells housing and protecting the wart. The latter either develops a blister underneath and falls off, or the damaged skin cells are discarded by the body, thereby also effectively removing the wart and the virus.

Wartie® Wart Remover contains the following materials:

Name	**Material**
Cap	PP
Cone	POM
Nose Piece	Bronze coated with Nickel
Ring	POM
Can	Aluminum

Wartie® Wart Remover is intended for topical treatment of common and plantar warts, using the following application times, which vary on the basis of the wart diameter:

	WART DIAMETER	**TREATMENT TIME**
Common warts and plantar warts on toes and arch of foot	Smaller than 3/32 in (2.5mm)	10 seconds
Common warts and plantar warts on toes and arch of foot	3/32 – 3/16 in (2.5 – 5.0 mm)	15 seconds
Common warts and plantar warts on toes and arch of foot	Larger than 3/16 in (5.0mm)	20 seconds
Calloused Plantar warts on heels and balls of feet	All sizes	40 seconds or less

Intended Use and Indication for Use Statement:

Wartie® Wart Remover is intended for over-the-counter treatment of common warts and plantar warts to be used in adults and children 4 years of age and older.

Application:
The product administers cryogens to the wart by way of an applicator.

Technological Characteristics:

Wartie® Wart Remover is a portable cryosurgical systems comprised of a canister containing a cryogen and an applicator that applies the cold to the wart to be treated for the over-the-counter treatment of common and plantar warts. The Wartie® Wart Remover employs a metal applicator used as cold retraction vehicle. This allow for pen-pointed accuracy in freezing the skin. Wartie® Wart Remover makes use a secured locking ring in order to assure mechanical safety of the product, and thermal safety precautions are associated with activation of the aerosol. Finally, the product uses thermal energy removed from skin at the anatomical site of a common wart and/or plantar wart.

Non-Clinical Testing:
The following tests were performed on the finished product:

- Stability test;
- Compatibility test.

Bench testing:

The following test was performed on the finished product:

- Comparative bench testing between Wartie® Wart Remover and the predicate devices using a biological tissue skin test model. Please note that the bench test has been conducted on Histofreezer® Wart Removal System, Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover, Wart Freeze (named in EU as Actifreeze), and Bozuuka Sub-Zero because aimed for both EU and US market. As indicated above, the device named "Actifreeze" in the bench test is available in US under the name "Wart Freeze", indivated as predicate device. Not being available in US, Bozuuka Sub-Zero cannot be selected as predicate device.

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The non-clinical and bench testing have supported the safety and efficacy of Wartie® Wart Remover.

Substantial Equivalence Information:

	Wartie® Wart Remover	**Wartner® Wart Removal system**	**Dr. Scholl's® Freeze Away TM Wart Remover**	**Histofreezer® Wart Removal System**	**Wart Freeze**
FDA 510(k) number	K140314	K032271	K031697	K023487	K130599
intended use comparison	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.
indications for use comparison	OTC treatment of common and plantar warts.	OTC treatment of common warts and plantar warts.	OTC treatment of common and plantar warts.	OTC treatment of common and plantar warts.	OTC treatment of common and plantar warts.
target population	Adults and Children 4+.	Adults and Children 4+.	Adults and Children 4+.	Adults and Children 4+.	Adults and Children 4+.
anatomical sites	Topical – Wart.	Topical – Wart.	Topical – Wart.	Topical – Wart.	Topical – Wart.

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energy used and/or delivered	Thermal energy removed from skin via a metal interface.	Thermal energy removed from skin via a sponge containing liquid gas.	Thermal energy removed from skin via a sponge containing liquid gas.	Thermal energy removed from skin via a sponge containing liquid gas.	Thermal energy removed from skin via a polypropylene applicator.
design	Device requiring activation and application. Metal tip provides pen-pointed accuracy.	Device requiring assembly, activation, and application.	Device requiring assembly, activation, and application.	Device requiring assembly, activation, and application.	Device requiring activation and application.
materials	DME from aerosol can applied to the skin through a metal core via a Nickel tip providing pen-point accuracy.	DME/Propane from aerosol can applied to the skin through a sponge core mounted on a plastic applicator.	DME/Propane from aerosol can applied to the skin through a sponge core mounted on a plastic applicator.	DME/Propane from aerosol can applied to the skin through a sponge core mounted on a plastic applicator.	DME from aerosol can applied to the skin through a polypropylene applicator.
biocompatibility	Established according to ISO 10993.	Established according to ISO 10993.	Established according to ISO 10993.	Established according to ISO 10993.	Established according to ISO 10993.

Comparison of Technological Characteristics:

The Wartie® Wart Remover is substantially equivalent to the Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover, Histofreezer® Wart Removal System, Wart Freeze devices for the same indications. All indicated devices are portable cryosurgical systems comprised of a canister containing a cryogen and an applicator that applies the cold to the wart to be treated for the over-the-counter treatment of common and plantar warts. The Wartie® Wart Remover, however, employs a metal applicator while Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover and Histofreezer® Wart Removal System employ a Polyethylene sponge/foam applicator; and Wart Freeze employs a polypropylene applicator.

Wartie® Wart Remover differs from the predicate devices in that the material of the cold retraction vehicle differs. While Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover and Histofreezer® Wart Removal System apply a cryogen to a sponge, and , Wart Freeze applies a polypropylene applicator; Wartie® Wart Remover applies the cryogen to a metal nose piece which allows efficient heat transfer to the skin.

This difference in technology has been evaluated in bench testing to determine the equivalence of the products, and market experience and other available devices show that the heat transfer via a metal core is a used and approved technology.

The method of freezing skin via a metal applicator allows for pen-pointed accuracy in freezing the skin.

As mentioned earlier, bench testing has shown the performance of Wartie® Wart Remover to be equivalent with abovementioned OTC technologies in terms of safety and efficacy, thereby supporting its OTC status.

While the technology employed by Wartie® Wart Remover differs from its predicates in that the product uses pure DME gas applied via a metal applicator, bench testing has shown equivalent performance for safety and efficacy on biological tissue. DME gas is also used by Wart Freeze but with a polypropylene applicator.

Note: The limitation of 4 years and older is an industry-wide limitation based on clinical data available for comparable products. The predicate device Wartner® Wart Removal System – K032271, as well as other OTC products have the same restriction. The clinical study carried out with Histofreezer® has shown the technology to be appropriate for pediatric patients (above the age of 4)[1]. A bench study, further discussed in section 18, has furthermore shown compared Wartie® Wart Remover with its predicate as well as other available products such as Histofreezer®, showing that its performance is within the parameters of Histofreezer® and, thereby, also applicable for patients above the age of 4. The bench study showing that Wartie® Wart Remover's metal probe does not adhere to the skin (also shown in section 18), thereby showing that there are no additional risks, further support the appropriate limitation to pediatric patients above the age of 4.

[1] Ricketti, J.C. et al. A Study of a New Method of Cryosurgical Treatment of Verrucae Plantaris. *The Lower Extremity*: Vol. 2 No. 3; 1995.

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Summary of Similarities:

The Wartie® Wart Remover has the following similarities with the Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover, Histofreezer® Wart Removal System and Wart Freeze:

- The same intended use and indication for use,
- The same warnings and contraindications,
- Available for over-the-counter use, and
- Destroy common warts and plantar warts by cryoablation.

In details:

- Wartie® Wart Remover and Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover, Histofreezer® Wart Removal System and Wart Freeze are intended for over- the-counter treatment of common warts and plantar warts to be used in adults and children 4 years of age and older.

- Wartner® Wart Removal System, Dr. Scholl's® Freeze Away TM Wart Remover, Wart Freeze and Histofreezer® Wart Removal System and Wartie® Wart Remover use a cryogen filled into an aerosol can in order to transform kinetic energy into thermal energy in order to remove a common wart or plantar wart by cryosurgery.

- Wartie® Wart Remover makes use a secured locking ring in order to assure mechanical safety of the product. A similar feature is also employed by the Wartner® Wart Removal System.

- In the predicate devices identified above as well as Wartie® Wart Remover, thermal safety precautions are associated with activation of the aerosol.

- Wartie® Wart Remover, as the predicates mentioned, uses thermal energy removed from skin at the anatomical site of a common wart and/or plantar wart.

- The label of the Wartie® Wart Remover has been developed to ensure consumer safety and is equivalent to the predicate device identified for this purpose.

- The safety and warning statements for the OTC predicate devices and for all the other predicate labeling device are similar.

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Conclusion:

Based on the information presented, it is concluded that the proposed product, Wartie® Wart Remover, is safe and effective for its intended use and is substantially equivalent to the predicate devices. It can be therefor considered substantially equivalent in intended use, indication for use, safety and affectivity profile, and labeling.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

YouMedical BV
% Ms. Kathleen Johnson
Medical Device Approvals Incorporated
P.O. Box 2042
Fairfield, Iowa 52556

Re: K140314
Trade/Device Name: Wartie® Wart Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 14, 2014
Received: May 16, 2014

Dear Ms. Johnson:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140314

Device Name

Indications for Use *(Describe)*

Wartie® Wart Remover is indicated for the over-the-counter treatment of common warts and plantar warts for patients aged 4 years and older.

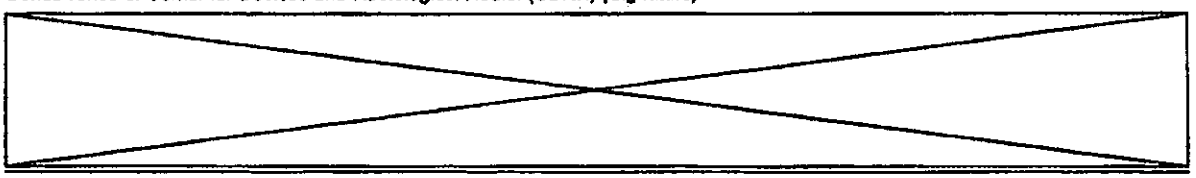
Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



Joshua C. Nipper -S