



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

August 14, 2015

YouMedical Corp BV  
% Ms. Kathleen Johnson  
Medical Device Approvals Incorporated  
P.O. Box 1124  
Bryn Mawr, Pennsylvania 19010

Re: K151309

Trade/Device Name: Wartie<sup>®</sup> Advanced Wart Remover  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: Class II  
Product Code: GEH  
Dated: May 11, 2015  
Received: May 18, 2015

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

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

**Indications for Use**

510(k) Number (if known)

Device Name

Wartie® Advaced Wart Remover

Indications for Use (Describe)

Wartie® Advanced Wart Remover is indicated for the over-the-counter treatment of common warts and plantar warts for patients ages 12 years and older.

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

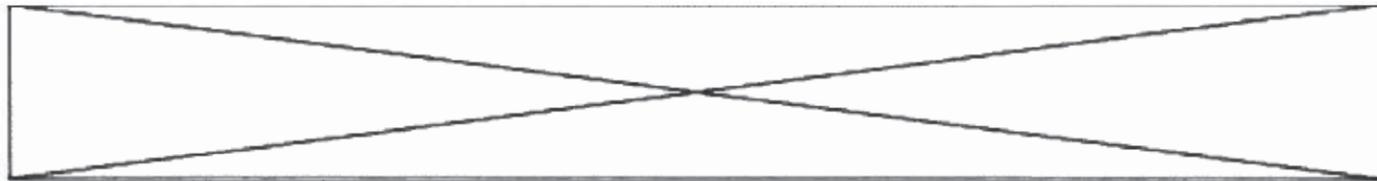
Prescription Use (Part 21 CFR 801 Subpart D)

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)



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**Premarket Notification 510(k) Summary**  
**Wartie® Advanced Wart Remover**

Sub. N.: TBD  
 Version: 1.0  
 Date: 11-May-15

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

<b>Submitter</b> 807.92(a)(1)	YouMedical Corp BV, Rijnsburgstraat 9-11, 1059AT Amsterdam, The Netherlands
<b>Contact Person</b>	Kathleen Johnson Medical Device Approvals, Inc. PO Box 1124 Bryn Mawr, PA 19010 kathleen@mdapprovals.com
Date Prepared	06/May/15
Trade Name 807.92(a)(2)	Wartie® Advanced Wart Remover
Common Name	OTC Wart Removal System
Classification Name 807.92(a)(2)	Cryosurgical unit, accessories
Classification Panel	General & Plastic Surgery
Product Code	GEH
Predicate Device 807.92(a)(3)	Wartie® Wart Remover K140314 Histofreezer® Wart Removal System K023487
Predicate Comparison	Wartie® Wart Remover K140314: Intended use, technology, materials, label.  Histofreezer® Wart Removal System K023487: Intended use, technology, materials.
Device Description 807.92(a)(4)	The Wartie® Advanced Wart Remover is an over the counter cryosurgery product (for the treatment of warts), to be used at home.  The device consists of: <ul style="list-style-type: none"> <li>• A pressurized canister filled with 50mL of the compressed liquid gas dimethyl ether with a custom application unit used to administer the cold delivered by the cryogen to the wart.</li> <li>• One 3 mL tube of conductive gel (also called gel).</li> <li>• Six disposable comfort pads.</li> <li>• Instructions for use in which you can read about the product how it works, how to use the product</li> </ul>



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**Wartie® Advanced Wart Remover**

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<p>Operating Principle</p>	<p align="center">to treat warts, warnings and limitations.</p> <p>Wartie® Advanced Wart Remover technology involves freezing a wart (common and/or plantar) using a very cold liquid gas (cryogen) that is released into a patented-pending applicator. The applicator becomes very cold and is able to freeze the skin. A tube of conductive gel that maximizes the freezing potential by directing and isolating the cold temperature onto the application area, thereby moisturizing the skin. The freezing of the skin causes damage to the cells housing and protecting the wart. The wart then both develops a blister underneath and then falls off, or the damaged skin cells are discarded by the body, thereby also effectively removing the wart and the virus.</p> <p>Six disposable comfort pads used to protect the tender plantar wart area after treatment has been completed in case of particularly sensitive skin.</p>
<p>Intended Use 807.92 (a)(5)</p> <p>Indications for Use</p>	<p>Wartie® Advanced Wart Remover is intended for over-the-counter treatment of common warts and plantar warts to be used in adults and children 12 years of age and older.</p>
<p>Technological Characteristics as compared to the predicate devices 807.92 (a)(6)</p>	<p>The Wartie® Advanced Wart Remover employs a metal applicator used as cold retraction vehicle. This allow for pen-pointed accuracy in freezing the skin. Wartie® Advanced Wart Remover makes use of a conductive gel to optimize relative freezing performance, a secured locking ring in order to assure mechanical safety of the pressurized canister, 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.</p> <p>DME applied to skin surface to freeze topical wart</p>
<p>Product Testing 807.92 (b)(1)</p>	<p>Biocompatibility per ISO 10993 Bench testing to show comparable freezing performance between subject device and predicates</p>
<p>Clinical Testing 807.92 (b)(2)</p>	<p>N/A</p>



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Wartie® Advanced Wart Remover**

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Version: 1.0  
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<b>Substantial Equivalence Information</b>			
	<b>Wartie® Advanced Wart Remover</b>	<b>Wartie® Wart Remover</b>	<b>Histofreezer® Wart Removal System</b>
510(k) number	Not Assigned	K140314	K023487
Intended Use	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.
Target population	Adults and Children 12+.	Adults and Children 4+.	Adults and Children 4+.
Energy used and/or delivered	Thermal energy removed from skin via a metal interface.	Thermal energy removed from skin via a metal interface.	Thermal energy removed from skin via a sponge containing liquid gas.
Design	Device requiring application of the gel, activation and application. Metal tip provides pen-pointed accuracy.	Device requiring activation and application. Metal tip provides pen-pointed accuracy.	Device requiring assembly, activation, and application.
Cryogen and applicator materials	DME from aerosol can applied to the skin through a metal core via a Nickel tip providing pen-point accuracy	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.
Summary of Technological Differences	The only notable technological differences involve the type of device applicator used to deliver the cryogen. The Histofreezer® Wart Removal System device uses a sponge and the Wartie systems use a metal tip. The subject device uses a conductive gel to moisten the skin whereas the predicates do not. Comfort pads are included in Wartie® Advanced Wart Remover to protect tender plantar warts after treatment. These technological differences do not create any new risks of safety or effectiveness for the user.		
Summary of similarities	All three devices have the same intended use and utilize the same type of technology.		
Conclusion 807.92 (b)(3)	The subject device is substantially equivalent to the predicate devices based on intended use, principle of operation, biological evaluation and non-clinical bench testing. Any identified differences do not constitute new risks of safety or effectiveness to the user.		