January 21, 2025

Medical Brands Laboratories B.V.
Pieternella Bouter
Chief Commercial Officer (CCO)
Weesperstraat 114
Diemen, 1112AP
Netherlands

Re: K242288
Trade/Device Name: Advanced Cryo Wart Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: August 2, 2024
Received: December 20, 2024

Dear Pieternella Bouter:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2025.01.21 11:14:35 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242288

Device Name

Advanced Cryo Wart Remover

Indications for Use *(Describe)*

The Advanced Cryo Wart Remover is designed as an over-the-counter (OTC) self-care device indicated for adults and children from the age of four years and older for the treatment of common and plantar warts.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510 (k) number K242288 Summary
(As required by 21 CFR 807.92)_v5.0

807.92(a)(1)

1. Submission Sponsor:

Medical Brands Laboratories B.V.
Weesperstraat 114,
1112 AP, Diemen,
The Netherlands
+31 (0)20 345 53 30
Drs. P. Bouter

2. Date Prepared: Up-dated January 2025 (v5.0)

807.92(a)(2)

3. Device Identification:

Trade/Proprietary Name:	Advanced Cryo Wart Remover
Common/Usual Name:	Cryogenic OTC Pen
510 (k) number:	K242288
Classification Name:	Layperson wart removal cryogenic device
Regulation Number:	21 CFR 878.4350
Product Code:	GEH, Unit, Cryosurgical, Accessories
Class:	II
Classification Panel:	General and Plastic Surgery (878.4350 - Cryosurgical unit and accessories)

807.92(a)(3)

4. Legally marketed Primary predicate device:

Device Name:	Wartie®
Proprietary Name:	Wartie® Wart Remover
510 (k) number:	K140314
Manufacturer:	YouMedical BV

510 (k) number K242288 Summary
(As required by 21 CFR 807.92)_v5.0

Regulation Number	21 CFR 878.4350
Product Code	GEH, Unit, Cryosurgical, Accessories

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

807.92(a)(4)

5. Description of the Subject Device

The Advanced Cryo Wart Remover is an over-the-counter (OTC) cryotherapy device designed for the treatment of common and plantar warts. The device includes:

- A 15 mL / 0.51 oz pressurized aerosol canister containing a freezing agent (1,1-Difluoroethane, Propane, and Isopentane).
- A metal tip that applies the cryogen directly to the wart
- Detailed instructions, including illustrated descriptions.

To activate the product, the lay user must, while holding the device facing downward, press the side buttons firmly five times in a row. Apply the cold metal tip for 20 seconds on warts located on the hands, tops of feet, and toes. Apply for 40 seconds on plantar warts in areas with thicker or calloused skin.

The device is non-sterile, reusable, and intended for home use by laypersons. No special training or sterilization is required for operation.

807.92(a)(5)

6. Indication for use and Intended Users of Subject Device

The Advanced Cryo Wart Remover is an over-the-counter (OTC) device indicated for adults and children from the age of four years and older for the treatment of common and plantar warts.

807.92(a)(5)

7. Indication for use Comparison

The subject device has the same indications for use as the predicate devices.

510 (k) number K242288 Summary
(As required by 21 CFR 807.92)_v5.0

807.92(a)(6)

8. Technological Comparison

The subject device has the same technological characteristics as the predicate devices. It shares the same intended use, mechanism of action, and technology as the predicate devices. Whereby the subject device share the following similar characteristics:

- Gas composition of cryogen; Mixture of DMPE - Dimethyl ether, Propane, Isobutane versus 1,1 Difluoroethane, Propane, Isopentane)

807.92(b)

9. Non-clinical Performance Data

To demonstrate safety and effectiveness of the Advanced Cryo Wart Remover and to show substantial equivalence to the predicate device, the following non-clinical tests were performed.

- Biocompatibility Testing per ISO 10993-1 – Supports biocompatibility of the device.
  - ISO 10993-5 (cytotoxicity)
  - ISO 10993-10 (irritation)
  - ISO 10993-10 (sensitization)
  - ISO 10993-17 (toxicological risk assessment (TRA))
  - ISO 10993-18 (chemical characterization)

Advanced Cryo Wart Remover passed the testing in accordance with:
Shelf Life Testing per ASTM D3090-72 – Supports shelf life of 36 months.

- Shelf life testing was based on device stability and functionality testing.

Transportation Testing per ASTM D4169

Bench Testing – Supports device performance.

- Advanced Cryo Wart Remover was subjected to comparative thermal performance testing that included thermoelectric testing to determine freeze temperature extremes, freeze temperature plateau, and freeze duration. The test provided data on both the temperature profile at the target surface and on the tissue freezing capacity of the device. The results of the tests demonstrated comparable performance to the predicate devices.

Label and IFU Comprehension Study – Supports device self-selection & labeling comprehension.

- A Flesch test was performed on the proposed labeling to ensure that the instructions were considered 'readable' to lay consumers. The test generated a Flesch Reading Ease score of 61.22, Flesch-Kincaid Grade Level of 7.26, and a ReadablePro rating of 'A'. According to the report created, the text has a Reach score of 100%, meaning that the text is readable for 100% of the addressable audience, equating to approximately 85% of the general public.

Human Factors Study – Supports safe usability of the device for lay-person use.

- A usability study compliant with EN ISO 8317:2004 was conducted to evaluate the design and safe use of the Advanced Cryo Wart Remover by lay consumers. The study assessed the device's usability, closure system, and instructions for use. Ten participants aged 50–70 found the device easy to use, citing its intuitive design, easy grip, and straightforward application. All users successfully operated the opening mechanism, requiring no changes to the device or instructions.
- A secondary usability study evaluated user interpretation of application time (one or two seconds) to ensure accurate device charging. Ten participants tested three methods (counting, phrase articulation, word articulation) five times each. Results showed that phrase and word articulation provided more consistent timing than counting. The study confirmed that the device design and Instructions for Use enable safe and effective use.
- A self assessment study including among 20 participants, 95% (19/20) accurately identified images of common and plantar warts.. All participants correctly confirmed their eligibility and understood the device's purpose and target users (common and plantar warts on hands and feet for ages 4+).

10. Statement of Substantial Equivalence

Based on the information presented, it is concluded that the Advanced Cryo Wart Remover is substantially equivalent to the primary predicate device Wartie® Wart Remover and the second primary predicate device Dr. Scholl's Skin Tag Remover.