January 21, 2021

Pronova Laboratories BV
% Stuart Goldman
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K201366
Trade/Device Name: Forwarts
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 21, 2020
Received: December 22, 2020

Dear Stuart Goldman:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201366

Device Name
Forwarts®

Indications for Use *(Describe)*
Forwarts® is indicated for the treatment of warts on hands (common warts) and feet (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.

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510(k) Summary

Forwarts®

1. Submission Sponsor

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3. Date Prepared

January 19, 2021

4. Device Identification

Trade/Proprietary Name:	Forwarts®
Common/Usual Name:	Cryosurgical unit and accessories
Classification Name:	Unit, Cryosurgical, Accessories
Regulation Number:	878.4350
Product Code:	GEH
Class:	Class 2
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Primary Predicate

Device name: Wart Freeze

510(k) number: K130599
Manufacturer: Koninklijke Utermohlen NV

Wart Freeze is an over the counter cryosurgery product for the treatment of common and plantar warts. The device consists of a pressurized dispenser containing 38 ml dimethyl ether (DME) with a polypropylene applicator that is permanently attached (fixed) to the dispenser.

Secondary Predicates

Device name: Compound W® Nitro-Freeze
510(k) number: K172373

Device name: Wartie® Wart Remover
510(k) number: K140314

Device name: Wartner® Wart Removal System
510(k) number: K032271

6. Indication for Use Statement

Forwarts® is indicated for the treatment of warts on hands (common warts) and feet (plantar warts).

7. Device Description

Forwarts® is a wart removal device that works by the principle of cryotherapy and is intended for the treatment of common and plantar warts. It delivers a precise cryogenic spray directly onto a wart or verruca which causes them to freeze and fall off the skin in approximately 10-14 days. The device consists of a pressurized aerosol can containing 35 ml dimethyl ether (DME). The aerosol can is held in a polypropylene shell (front and back). The front shell contains a distance holder for a safe and regulated application and a visor to point and limit the spray pattern. The translucent back shell contains a ridge for safe handling. The valve system will be extended by an actuator to point and minimize the spray pattern. Forwarts® is supplied with ten (10) protection patches per device to be placed around the wart prior to treatment to help prevent damage of healthy skin. Forwarts® is supplied non-sterile and not intended to be sterilized by the end user. The Forwarts® nozzle should be cleaned after each use with rubbing alcohol (70%).

8. Substantial Equivalence Discussion

The following table compares Forwarts® to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	Forwarts®	Wart Freeze / Koninklijke Utermohlen NV	Compound W® Nitro-Freeze / Medtech Products Inc.	Wartie® Wart Remover / YouMedical B.V.	Wartner® Wart Removal System / Wartner USA B.V.	Comparison
510(k) Number	K201366 (pending)	K130599	K172373	K140314	K032271	N/A
Product Code	GEH, Unit, Cryosurgical, Accessories	GEH, Unit, Cryosurgical, Accessories	GEH, Unit, Cryosurgical, Accessories	GEH, Unit, Cryosurgical, Accessories	GEH, Unit, Cryosurgical, Accessories	Same
Regulation Number	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	Same
Indications for Use	Forwarts® is indicated for the treatment of warts on hands (common warts) and feet (plantar warts).	Wart Freeze is indicated for the removal of common and plantar warts	Compound W® Nitro-Freeze is intended for over-the-counter treatment of common warts and plantar warts in adults and children four years of age or older	Wartie® Wart Remover is indicated for the over-the-counter treatment of common warts and plantar warts, for patients aged 4 years and older.	WARTNER® Wart Removal System is indicated for the over-the-counter treatment of common warts and plantar warts.	Same
OTC or Rx	OTC	OTC	OTC	OTC	OTC	Same
Technological Characteristics	Pressurized gas canister that	Pressurized gas canister that applies	Pen with pressurized cartridge that	Pressurized gas canister that	Pressurized gas canister that	Similar; Differences in cryogen and cold

Attribute	Forwarts®	Wart Freeze / Koninklijke Utermohlen NV	Compound W® Nitro-Freeze / Medtech Products Inc.	Wartie® Wart Remover / YouMedical B.V.	Wartner® Wart Removal System / Wartner USA B.V.	Comparison
	applies extreme cold to target; Cryogen (liquefied dimethyl ether, BP = -24°C) aerosol spray is applied directly to the wart, causing rapid freezing.	extreme cold to target; Cryogen (liquefied dimethyl ether, BP = -24°C) is applied directly to the wart, causing rapid freezing.	applies extreme cold to target; Cryogen (liquefied nitrous oxide, BP = -89°C) is loaded onto a foam applicator, which is applied to the wart, causing rapid freezing.	applies extreme cold to target; Cryogen (liquefied dimethyl ether, BP = -24°C) is used to refrigerate a steel tip, which is applied to the wart, causing rapid freezing.	applies extreme cold to target; Cryogen (liquefied dimethyl ether / propane mixture, BP = -24°C / -48°C) is loaded onto a foam applicator, which is applied to the wart, causing rapid freezing.	application technique. The added wind chill effect of Forwarts' DME aerosol spray results in lower temperatures compared to Wart Freeze.
Mechanism of Action	Cryotherapy Rapid freezing followed by slow thawing, causing cell injury and ischemic necrosis.	Cryotherapy; Rapid freezing followed by slow thawing, causing cell injury and ischemic necrosis.	Cryotherapy; Rapid freezing followed by slow thawing, causing cell injury and ischemic necrosis.	Cryotherapy; Rapid freezing followed by slow thawing, causing cell injury and ischemic necrosis.	Cryotherapy; Rapid freezing followed by slow thawing, causing cell injury and ischemic necrosis.	Same
Materials with direct patient contact	DME, polypropylene Optional protection patch: PE foam	DME and polypropylene	Nitrous oxide and PU foam	Nickel	DME, propane and PU foam	Similar to primary predicate device; Different from supplemental predicate devices.

Attribute	Forwarts®	Wart Freeze / Koninklijke Utermohlen NV	Compound W® Nitro-Freeze / Medtech Products Inc.	Wartie® Wart Remover / YouMedical B.V.	Wartner® Wart Removal System / Wartner USA B.V.	Comparison
Biocompatibility	Established conform ISO 10993-1	Established conform ISO 10993-1	Established conform ISO 10993-1	Established conform ISO 10993-1	Established conform ISO 10993-1	Same
Maximum allowed consecutive treatments (2-week interval)	4	4	3	3	3	Similar
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Re-Usable	Yes; Except for optional protection patch	Yes; includes applicator	Yes; except for disposable applicator foam tips	Yes;	Yes; except for disposable applicator foam tips	Similar; Skin-contacting tips of Forwarts and Wart Freeze are re-used and to be cleaned. Those of Compound W® Nitro-Freeze and Wartner® Wart Removal System are disposable.

Attribute	Forwarts®	Wart Freeze / Koninklijke Utermohlen NV	Compound W® Nitro-Freeze / Medtech Products Inc.	Wartie® Wart Remover / YouMedical B.V.	Wartner® Wart Removal System / Wartner USA B.V.	Comparison
Thermal Performance Testing	Measured attributes included: freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size	Measured attributes included: Freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size	Measured attributes included: freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size	Measured attributes included: freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size	Measured attributes included: freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size	Similar; Forwarts® achieves thermal performance characteristics within the ranges of the predicates demonstrating comparable efficacy. Temperatures achieved demonstrating that there are no new questions of safety.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Forwarts® and to show substantial equivalence to the predicate device, Pronova Laboratories BV completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. Forwarts® passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- 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)

  Based on the chemical characterization testing and TRA that was performed; therefore, no carcinogenicity testing was required.

- Shelf Life Testing per ASTM D3090-72 – Supports shelf life of twenty months.

  Shelf life testing was based on device stability and functionality testing when stored under worst case simulated conditions. The results of the test demonstrate device stability for twenty months.

- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained.

  Forwarts® in its final shipping configuration was subjected to impact, drop, vibration and low-pressure testing under simulated transport conditions. The results of the testing demonstrated that the packaging configuration is suitable to maintain device integrity.

- Bench Testing – Supports device performance.

  Forwarts® was subjected to comparative thermal performance testing that included thermoelectric testing and a simulated skin model to determine freeze temperature extreme, freeze temperature plateau, freeze duration, freeze cycle length and freeze spot size. 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.

- Self-selection / Label Comprehension Study – Supports device self-selection and labeling comprehension.

  A self-selection study was performed on Forwarts® to demonstrate a success rate of at least 90% when used as indicated. The study subjects were provided with the Forwarts® labeling (package and instructions for use) for this study.

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

  A Formative Study was conducted on Forwarts® that included Simulated Use Testing focusing on Critical Tasks, combined with Contextual Enquiry and a semi-guided interview with test subjects. A Human Factor Validation Test was then performed to validate that Forwarts® is safe for its intended use.

10. Statement of Substantial Equivalence

Forwarts® has the same intended use as the Wart Freeze predicate device, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated that Forwarts® is as safe and effective as the predicate device. Therefore, Forwarts® is substantially equivalent to the predicate device.