November 2, 2017

Medtech Products Inc.
Mr. Vincent Argiro
Director, Regulatory Affairs
660 White Plains Rd.
Suite 250
Tarrytown, New York 10591

Re: K172373
Trade/Device Name: Compound W Nitro-Freeze
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 27, 2017
Received: October 30, 2017

Dear Mr. Argiro:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172373

Device Name
Compound W® Nitro-Freeze

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MEDTECH
A PrestigeBrands COMPANY

Section 5 – 510(k) Summary

Compound W® Nitro-Freeze

K # K172373

1. Submitter

Name & Address:	Medtech Products Inc. 660 White Plains Road Tarrytown, NY, 10591
Contact:	Vincent Argiro, RAC
Title:	Director, Regulatory Affairs
Phone number:	(914) 524-8721
Email:	vargiro@prestigebrands.com

2. Date Prepared August 4, 2017

3. Device Identification

Trade/Proprietary Name:	Compound W® Nitro-Freeze
Common/Usual Name:	Over-the-counter cryogenic wart remover
Classification Name:	Cryosurgical unit and accessories
Regulation Number:	21 C.F.R. § 878.4350
Product Code:	GEH [Unit, Cryosurgical, Accessories]
Device Class:	Class II
Classification Panel:	General & Plastic Surgery Devices

4. Legally Marketed Predicate Device(s)

Predicate No. 1:	Wartner® Wart Removal System (K032271), Product Code GEH
Predicate No. 2:	Wartie® Wart Remover (K140314), Product Code GEH

5. Device Description

Compound W® Nitro-Freeze is a pen-like cryogenic device that utilizes pressurized nitrous oxide (N_2O, liquefied) to destroy wart tissue through evaporative cooling when the cryogen is delivered via a disposable foam applicator tip. Each Compound W® Nitro-Freeze device is supplied in an outer carton with an Instructions-for-Use leaflet and a bag containing replacement tips.

6. Intended Use

The Compound W® Nitro-Freeze is an over-the-counter (OTC) device that is intended to be used by lay people to treat common warts and plantar warts.

The Compound W® Nitro-Freeze bears the following indications for use statement:

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.

Compound W® Nitro-Freeze has the same intended use as the predicate devices and very minor differences between Compound W® Nitro-Freeze and the predicates with respect to the wording of the indications for use statements do not alter the devices' intended therapeutic effect.

7. Substantial Equivalence Discussion

The following table compares Compound W® Nitro-Freeze to the predicate devices with respect to intended use and technological characteristics. This comparison of the devices provides detailed information demonstrating the basis for the determination of substantial equivalence.

Table 5-1: Comparison of Characteristics

	Proposed Device	Predicate 1	Predicate 2	Differences
Trade Name /Device Name	Compound W® Nitro-Freeze	Wartner® Wart Removal System	Wartie® Wart Remover	N/A
510(k) Number	TBD	K032271	K140314	N/A
Date Cleared	90 days from date of receipt by FDA[1]	09/10/2003	06/12/2014	N/A
Original applicant	Medtech Products Inc.	Wartner USA B.V.	YonMedical B.V.	N/A
REGULATORY CLASSIFICATION				
Regulatory Class	Class II	Class II	Class II	None
Name of Generic Device Type	Cryogenic wart remover	Cryogenic wart remover	Cryogenic wart remover	None

[1] Projected based on Section 510(k) of the FDCA

Regulation	21 CFR § 878.4350	21 CFR § 878.4350	21 CFR § 878.4350	None
Product Code	GEH	GEH	GEH	None
Applicable Performance Standards or Special Controls	N/A	N/A	N/A	None
DEVICE DESCRIPTION – SUBSTANTIAL EQUIVALENCE COMPARATORS				
Intended Use	Allow consumers direct access to a safe and effective means to remove common warts and plantar warts.	Allow consumers direct access to a safe and effective means to remove common warts and plantar warts.	Allow consumers direct access to a safe and effective means to remove common warts and plantar warts.	None
OTC or Rx	OTC	OTC	OTC	None
Indications for Use	For over-the-counter treatment of common warts and plantar warts in adults and children four years of age or older.	For the over-the-counter treatment of common warts and plantar warts.	For the over-the-counter treatment of common warts and plantar warts for patients aged 4 years and older.	None
Target Population	Adults and children 4 years and older	Adults and children 4 years and older	Adults and children 4 years and older	None
Technological Characteristics	Pressurized gas to generate extreme cold at an applicator tip	Pressurized gas to generate extreme cold at an applicator tip	Pressurized gas to generate extreme cold at an applicator tip	None
DEVICE DESCRIPTION – DESIGN FEATURES				
Energy	Thermal (removal of heat from treated skin)	Thermal (removal of heat from treated skin)	Thermal (removal of heat from treated skin)	None
Design / Presentation	Pen-like device with disposable foam applicators	Table-top device with disposable foam applicators	Pen-like device with reusable applicator bead	Minor (similar to both predicates)
Mode of Action	Destruction of infected cells by freezing	Destruction of infected cells by freezing	Destruction of infected cells by freezing	None
Directions for use	Place device on flat surface; push pen into cap for 2 sec.; remove from cap and use device to	Place device on flat surface; assemble tip and handle; push tip/handle into device for 2-3	Place on flat surface; re-align cap; press cap down for 2 sec.; remove cap and	Minor (similar to both predicates)

	apply tip to wart	sec.; use handle to apply tip to wart	use device to apply tip to wart	
Duration of treatments	Dependent upon size and location of wart (max 20 sec. for common warts and max 40 sec. for plantar warts	Dependent upon size and location of wart (max 20 sec. for common warts and max 40 sec. for plantar warts	Dependent upon size and location of wart (max 20 sec. for common warts and max 40 sec. for plantar warts	None
Cryogen and Applicator	Nitrous oxide delivered via foam applicator	Dimethyl ether and propane delivered via foam applicator	Dimethyl ether used to cool a metal applicator bead	Yes (see discussion in Sections 8-10 of this summary)
Temperature at tip (after 40 seconds, in bench testing)	-82.83°C	-33.06°C	-24.01°C	Yes (see discussion in Sections 8-10 of this summary)
Gas flammability	No	Yes	Yes	Improved safety
Pressure release feature	Yes	No	No	Yes (see discussion in Section 8 of this summary)
Multiple Use Device	Yes	Yes	Yes	None
Sterile Device	No	No	No	None
Leaflet included	Yes	Yes	Yes	None
Use environment	Home	Home	Home	None
Anatomical site of use	Topical – wart	Topical – wart	Topical – wart	None
Electricity or radiation used	No	No	No	None

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent (SE) when it has the same intended use and technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), any differences between the subject device and the cited predicates do not raise different questions of safety or effectiveness and data (including clinical data) establishes that the device is as safe and effective as the predicates. It is on this basis that Compound W® Nitro-Freeze is SE to the cited predicate devices.

8. Non-Clinical Performance Data

While the design differences between Compound W® Nitro-Freeze and the predicates are minor and non-clinical testing is therefore unnecessary, the cryogenic performance of the device has been properly validated. An *in vitro* experiment was conducted to determine the temperature generated by Compound W® Nitro-Freeze in comparison to three other over-the-counter cryogenic wart removers currently on the market: the predicates, Wartner and Wartie Wart Remover, and Urgo

(marketed in the U.S. as "Wart Freeze" under K130599). Product samples were tested at room temperature after being activated and introduced to an application substrate using a calibrated measuring instrument with a thermocouple sensor. This study clearly demonstrated the freezing performance of Compound W® Nitro-Freeze throughout the maximum treatment time of 40 seconds; the product generated temperatures ranging from -86.08°C (T=0) to -82.83°C (T=40) versus -28.82°C to -33.06°C (Wartner), -20.38°C to -24.01°C (Wartie Wart Remover), and -24.36°C to -1.93°C (Urgo).

The performance of the device's pressure release feature was validated in a study involving placement of 20 device samples in a laboratory oven at progressive temperatures of 35°C, 40°C, and 50°C or 38°C and 50°C for 24-hour periods. [10 samples started at 35°C and 10 samples started at 38°C; devices that were not disarmed moved on to the next stage in their respective test groups.] After each exposure period, the devices were cooled at room temperature and then tested to determine which had been successfully disarmed. To determine whether a device was disarmed, the analyst attempted to load (charge) the applicator tip with cryogen; if no cryogen remained in the canister, the device was considered disarmed. As intended, no devices were disarmed at 35°C and all were disarmed at either 38°C, 40°C or 50°C.

The non-clinical testing of Compound W® Nitro-Freeze demonstrates the device's freezing performance and the performance of its pressure release feature and therefore supports the substantial equivalence of Compound W® Nitro-Freeze to the cited predicates.

9. Clinical Performance Data

While there are no differences in intended use and technological characteristics between the Compound W® Nitro-Freeze and the predicates that necessitate conducting a clinical trial, clinical data was provided in the 510(k) submission.

A single-center, randomized, multi-arm study in 138 patients (124 per-protocol) was conducted to compare the safety and effectiveness of Compound W® Nitro-Freeze to two over-the-counter cryogenic wart treatments available in the U.S. and abroad (the predicate devices, Wartner and Wartie Wart Remover). That study involved 1-3 treatments with the selected product according to its labeled instructions (second and third treatments only if needed), each followed by evaluator assessments. The results are shown in the table below.

Table 5-2: Primary effectiveness criterion in Study no. 14E2344

Treatment	Cured after X treatment(s)			Not cured after 3 treatments
	X=1	X=2	X=3	
Nitro-Freeze	34.0% (17/50)	28.0% (14/50)	20.0% (10/50)	18.0% (9/50)
Wartner	10.5% (4/38)	18.4% (7/38)	18.4% (7/38)	52.6% (20/38)
Wartie	13.9% (5/36)	8.3% (3/36)	30.6% (11/36)	47.2% (17/36)

This study demonstrated statistically significant superior effectiveness for Compound W® Nitro-Freeze ("Pixie") versus Wartner and Wartie in both overall wart clearance (82.0% vs. 47.4% and 52.8%, respectively after final treatment, p = 0.001) and first-treatment wart clearance (34.0% vs. 10.5% and 13.9%, p = 0.013) with no serious product-related adverse events recorded and an increase in only minor treatment-related symptoms (i.e., wart-site blistering, pain, and burning sensation). With more people experiencing wart removal after one treatment with Compound W® Nitro-Freeze than after two treatments with either of the comparators, any modest increase in non-serious adverse events can be considered offset by the significant increase in product effectiveness.

Study no. 14E2344 confirms and demonstrates that Compound W® Nitro-Freeze is substantially equivalent to the legally marketed predicate devices.

10. Statement of Substantial Equivalence

Compound W® Nitro-Freeze has the same intended use as the predicate devices, Wartner (K032271) and Wartie Wart Remover (K140314), and utilizes the same basic principle of operation (introduction of extreme cold to destroy infected tissue). Like the predicates, Compound W® Nitro-Freeze uses pressurized gas as a cryogen, which it delivers using a disposable foam applicator – the same delivery method employed by the predicate, Wartner. Compound W® Nitro-Freeze and the predicate devices are of roughly the same size and shape and require depression of a device component for 2/3 seconds to release the cryogen and charge the applicator tip, and all three employ the same size- and location-dependent application times.

Although the design of Compound W® Nitro-Freeze relies on a different cryogen than the predicates (nitrous oxide vs. dimethyl ether and propane or dimethyl ether alone), that difference does not raise any new questions of safety and effectiveness that are not associated with the predicate devices and the non-clinical and clinical data provided in this submission demonstrate that Compound W® Nitro-Freeze is as safe and effective as the predicates. Compound W® Nitro-Freeze is therefore substantially equivalent to the cited predicate devices.