November 6, 2024

Medtech Products Inc.
Vincent Argiro
Associate Vice President, Regulatory Affairs
660 White Plains Road
Suite 250
Tarrytown, New York 10591

Re: K242803
Trade/Device Name: Compound W Skin Tag Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: September 17, 2024
Received: September 17, 2024

Dear Vincent 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 (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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2024.11.06 06:19:59 -05'00'

For
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.

510(k) Number *(if known)*
K242803

Device Name
Compound W Skin Tag Remover

Indications for Use *(Describe)*
Compound W Skin Tag Remover is intended for the OTC treatment of skin tags in adults age 22 years 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.

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"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."

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Section 5 – 510(k) Summary

Compound W® Skin Tag Remover

K # K242803

1. Submitter

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

2. Date Prepared 06 November 2024

3. Device Identification

Trade/Proprietary Name:	Compound W® Skin Tag Remover
Common/Usual Name:	Over-the-counter cryogenic skin tag 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)

Freeze'n Clear Skin Clinic Warts & Tags (K211099, currently marketed in the U.S. as “Dr. Scholl’s Freeze Away Skin Tag Remover”), Product Code GEH

5. Device Description

Compound W® Skin Tag Remover is a cryogenic device intended to remove acrochordons (skin tags) via epidermal cryotherapy, destroying target epidermal cells by using extremely cold temperatures. The device contains a non-replaceable, non-refillable aluminum canister holding the gases dimethyl ether and propane. Activation of the device ejects a dose of the gases into a disposable polyurethane foam applicator tip, resulting in freezing of the applicator to approximately -30°C. The cold applicator tip is placed on the skin tag, thus destroying the target tissue. Each Compound W® Skin Tag Remover device is supplied in a paperboard carton with eight disposable tips, plastic tweezers, adhesive "Tag Target" skin-protecting discs, and an Instructions-for-Use leaflet.

6. Intended Use/Indications for Use

Compound W® Skin Tag Remover has the same intended use as the predicate device: to allow consumers direct access to a safe and effective means to remove skin tags. The specific wording of the proposed Compound W® Skin Tag Remover Indications for Use statement is nearly identical to that associated with the predicate device—with the only difference being that the predicate is labeling for both wart and skin tag removal while the proposed Compound W device will be labeled only for skin tags, and the addition of a specific lower age limit—and therefore does not create an intended use for the device that differs from the predicate.

The Compound W® Skin Tag Remover bears the following Indications for Use statement:

> *Compound W® Skin Tag Remover is intended for over-the-counter treatment of skin tags in adults age 22 years or older.*

In summary, Compound W® Skin Tag Remover has the same intended use as the predicate device and very minor differences in the wording of the Indications for Use statements between Compound W® Skin Tag Remover and the predicate do not alter the devices' intended therapeutic effect.

7. Substantial Equivalence Discussion

The following table compares Compound W® Skin Tag Remover to the predicate device 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 Device	Differences
Trade Name /Device Name	Compound W® Skin Tag Remover	Freeze'n Clear Skin Clinic Warts & Tags	N/A
510(k) Number	TBD	K211099	N/A

Date Cleared	90 days from date of receipt by FDA[1]	06/17/2022	N/A
Original applicant	Medtech Products Inc.	CryoConcepts LP	N/A
REGULATORY CLASSIFICATION			
Regulatory Class	Class II	Class II	None
Name of Generic Device Type	Cryogenic skin tag remover	Cryogenic skin tag remover	None
Regulation	21 CFR § 878.4350	21 CFR § 878.4350	None
Product Code	GEH	GEH	None
Applicable Performance Standards or Special Controls	N/A	N/A	None
DEVICE DESCRIPTION – SUBSTANTIAL EQUIVALENCE COMPARATORS			
Intended Use	Allow consumers direct access to a safe and effective means to remove skin tags.	Allow consumers direct access to a safe and effective means to remove skin tags.	None
OTC or Rx	OTC	OTC	None
Indications for Use	For the OTC treatment of skin tags in adults age 22 years and older.	For the OTC treatment of common warts, plantar warts, and skin tags.	Minor: The predicate has an additional intended use for wart removal (though the marketed version has only the skin tag indication) with no specified age limit.
Technological Characteristics	Pressurized gas blend to generate extreme cold at an applicator tip	Pressurized gas blend 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)	None
Package Contents	Table-top device with disposable foam applicators, tweezers, Tag Targets, and IFU leaflet	Table-top device with disposable foam applicators, tweezers, and IFU leaflet	Minor: The proposed device has the adhesive paper Tag Targets as an additional safety feature.
Mode of Action	Destruction of target skin cells by freezing	Destruction of target skin cells by freezing	None

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

Directions for use	Attach applicator tip to handle; press actuator down for 2-3 seconds; pull skin tag away from the body with supplied tweezers and apply applicator tip to skin tag base continuously for 40 seconds	Attach applicator tip to handle; press actuator down for 3-5 seconds; wait 15 seconds; pull skin tag away from the body with supplied tweezers and apply applicator tip to skin tag base continuously for 40 seconds	Minor
Duration of treatments for Skin Tags	40 seconds	40 seconds	None
Cryogen and Applicator	Dimethyl ether and propane delivered via foam applicator	Dimethyl ether, propane, and isobutane delivered via foam applicator	Yes (see discussion in Section 8 of this summary)
Average Temp at tip (end of treatment time)	-30.5°C	-28.1°C	Minor
Sterile Device	No	No	None
Leaflet included	Yes	Yes	None
Use environment	Home	Home	None
Anatomical site of use	Skin	Skin	None
Electricity or radiation used	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 predicate do not raise different questions of safety or effectiveness and bench testing data establishes that the device is as safe and effective as the predicate. It is on this basis that Compound W® Skin Tag Remover is SE to the cited predicate device.

8. Non-Clinical Performance Data

To validate the cryogenic performance of Compound W® Skin Tag Remover, an *in vitro* experiment was conducted to determine the temperature generated by Compound W® Skin Tag Remover in comparison to the cited predicate device. Product samples were tested at room temperature after being activated and introduced to a measuring instrument with a thermocouple sensor. This study clearly demonstrated the superior freezing performance of Compound W® Skin Tag Remover

throughout the maximum treatment time of 40 seconds; the proposed product generated temperatures ranging from -30.9°C (T=0 seconds) to -30.1°C (T=55 second, or 15 seconds post treatment) versus -28.8°C to -27.8°C (predicate). Further, Compound W® Skin Tag Remover delivered an average temperature 2.4 degrees colder than the predicate in this study at the end of the 40-second treatment (-30.5°C at 40 seconds for Compound W® Skin Tag Remover vs -28.1°C for the predicate at 55 seconds due to its 15-second pre-treatment hold time).

Additionally, in accordance with ISO 10993, biocompatibility testing (cytotoxicity, skin irritation, and sensitization) was done on the canister as well as the adhesive Tag Target discs, showing the components are appropriate for their intended uses.

Finally, to confirm the ability of intended users to self-select, self-diagnose, and safely use the device, Human Factors Validation testing was conducted. The findings of that study (50 participant volunteers from the general population, including 15 intended users and 35 non-intended users) demonstrate that the user interface for Compound W Skin Tag Remover, including the labeling, supports safe and effective use for the intended users in the intended use environment.

The non-clinical testing of Compound W® Skin Tag Remover demonstrates the device's freezing performance, the suitability of its user interface, and the biocompatibility of its components and therefore supports the substantial equivalence of Compound W® Skin Tag Remover to the cited predicate.

9. Clinical Performance Data

There are no differences in intended use and technological characteristics between the Compound W Skin Tag Remover and the predicate that necessitates conducting a clinical trial to establish substantial equivalence.

10. Statement of Substantial Equivalence

Compound W® Skin Tag Remover has the same intended use as the predicate device, Freeze'n Clear Skin Clinic Warts & Tags (K211099, currently marketed in the U.S. as "Dr. Scholl's Freeze Away Skin Tag Remover") and utilizes the same basic principle of operation (introduction of extreme cold to destroy target tissue). Like the predicate, Compound W® Skin Tag Remover uses a combination of pressurized gases as a cryogen, which it delivers using a disposable foam applicator – the same delivery method employed by the predicate. Compound W® Skin Tag Remover and the predicate device are of roughly the same size and shape and require depression of a device component for a few seconds to release the cryogen and charge the applicator tip, and both employ the same application time for skin tags.

Although the design of Compound W® Skin Tag Remover relies on one fewer gas than the predicate (dimethyl ether and propane vs. dimethyl ether, propane, and isobutane), that difference does not raise any new questions of safety and effectiveness that are not associated with the predicate device. The non-clinical data provided in this submission demonstrate that Compound W® Skin Tag

Remover delivers a comparable temperature and is therefore as safe and effective as the predicate device, and the Human Factors Validation test demonstrates that the product interface supports safe and effective use for the intended users in the intended use environment.

As such, Compound W® Skin Tag Remover is substantially equivalent to the cited predicate device.