DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 15, 2016

MedTech Products, Inc.
% Ms. Kathryn Coressel
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400.
Austin, Texas 78701

Re: K161294
Trade/Device Name: Compound W Wart Removal System Dual Power
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: July 29, 2016
Received: August 2, 2016

Dear Ms. Coressel:

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 Part 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 Parts 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" (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.

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,

Christopher J. Ronk -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161294

Device Name
Compound W® Wart Removal System Dual Power

Indications for Use *(Describe)*
For the over-the-counter removal 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.

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Section 5 – 510(k) Summary

Compound W® Wart Removal System Dual Power

K # _161294_____

1. Submission Sponsor

MedTech Products Inc.

660 White Plains Road

Tarrytown, NY, 10591

USA

Phone number: (914) 524-6836

Contact: Czarina Ochoa

Title: Regulatory Affairs Manager

2. Submission Correspondent

Emergo Global Consulting, LLC

816 Congress Avenue, Suite 1400

Austin, TX 78701

Cell Phone: PHONE

Office Phone: (512) 327-9997

Contact: Kathryn A Coressel, Senior Consultant, RA

Email: project.management@emergogroup.com

3. Date Prepared

September 14, 2016

4. Device Identification

Trade/Proprietary Name:	Compound W® Wart Removal System Dual Power
Common/Usual Name:	OTC Wart Removal System
Classification Name:	Cryosurgical unit and accessories
Regulation Number:	878.4350
Product Code:	GEH
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Dr Scholl's® Dual Action Freeze Away™ Wart Remover (K052259)

6. Device Description

The Compound W® Wart Removal System Dual Power is a cryosurgical system for the over-the-counter removal of common and plantar warts.

Compound W® Wart Removal System Dual Power consists of the following:

- Pressurized aerosol spray canister with a mixture of dimethyl ether and propane (K032271)
- Reusable actuator/cap that releases the cryogen onto the disposable applicators
- Disposable foam applicators
- Salicylic acid gel wart remover provided in a squeeze tube (in compliance with OTC monograph 21 CFR 358 subpart B)
- Comfort pads
- Instruction Leaflet

7. Indication for Use Statement

Compound W® Wart Removal System Dual Power is intended for the over-the-counter removal of common and plantar warts.

8. Substantial Equivalence Discussion

The following table compares the Compound W® Wart Removal System Dual Power to the predicate device with respect to indications for use, principles of operation, technological characteristics, and materials . The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Schering-Plough HealthCare Products, Inc.**	**MedTech Products, Inc.**	**Significant Differences**
Trade Name	Dr Scholl's Dual Action Freeze Away Wart Remover	Compound W® Wart Removal System Dual Power	
510(k) Number	K052259	TBD	Not Applicable
Product Code	GEH	SAME	NONE
Regulation Number	878.4350	SAME	NONE
Regulation Name	Cryosurgical unit and accessories	SAME	NONE
Indications for Use	Dr. Scholl's® Dual Action Freeze Away TM Wart Remover is indicated for the over-the-counter removal of common and plantar warts.	Compound W® Wart Removal System Dual Power is indicated for the over-the-counter removal of common and plantar warts.	SAME
Presentation of kit	Kit contains both the cryogen spray and salicylic acid components in the same kit.	SAME	NONE
Sterile	No components are provided as sterile.	SAME	NONE
Single-Use	Only the disposable applicators are single-use.	SAME	NONE
Target Population	Adults and children 4 or older	SAME	NONE
Biocompatibility	Complies with ISO 10993	SAME	NONE
Cryogen spray			
Application	Portable cryosurgical system comprised of an aerosol pressurized canister containing cryogen and an applicator that applies the cryogen to the wart.	SAME	NONE

Manufacturer	Schering-Plough HealthCare Products, Inc.	MedTech Products, Inc.	Significant Differences
Trade Name	Dr Scholl's Dual Action Freeze Away Wart Remover	Compound W® Wart Removal System Dual Power	
Formulation	A mixture of dimethyl ether and propane	SAME	NONE
Freeze time	Dependent upon type and size of wart	Identical treatment times as predicate	NONE
Salicylic Acid			
Application	Post cryo-treatment with a reusable applicator to apply the acid to the wart.	Application is via a squeezable tube	Difference does not raise new concerns for safety or effectiveness.
Formulation	A 17% /salicylic acid **solution**	A 17% /salicylic acid **gel**	Difference does not raise new concerns for safety or effectiveness.
Frequency of Use	One drop of the liquid can be applied to the wart 24 hours post cryo-treatment.	Apply 1 drop at a time to cover the wart. Repeat once or twice a day as needed.	Difference does not raise new concerns for safety or effectiveness.