



Food and Drug Administration
10903 New Hampshire Avenue
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Koninklijke (Royal) Utermöhlen
% Dr. K R Michael, Pharm.D., M.Sc.
KRM Associates
17751 Frondosa Drive
San Diego, California 92128

November 6, 2015

Re: K152203

Trade/Device Name: Utermöhlen Cryo Professional
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: October 12, 2015
Received: October 14, 2015

Dear Dr. Michael:

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.

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,

Joshua C. Nipper -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

Indications for Use

510(k) Number

K152203

Device Name

UTERMÖHLEN CRYO PROFESSIONAL

Indications for Use

The product is indicated for the removal of the following skin lesions:

- Verrucae plantaris
- Verrucae Plana
- Verrucae vulgaris
- Mollescum contagiosum
- Skin tags
- Actinic keratosis
- Genital warts
- Lentigo
- Seborrhoeic Keratosis

Type of Use

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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510k Summary

Device name: Utermöhlen Cryo Professional
 Common Name: Portable Cryosurgery System for professional use
 Class: II
 Panel: GEH
 510k K152203
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1. Submitter

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 Netherlands

2. US Contact

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 San Diego, California 92128
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 Tel: 858 487 5676

3. Device Name(s)

Utermöhlen Cryo Professional

4. Common Name

Portable cryosurgery system for professional use

5. Class: II

6. Panel: GEH

7. Predicate device

The following predicate devices are legally commercialised / marketed in the US.

510k	K982358	K990877	K982506
Name of device	Histofreezer device	Histofreezer device	Verruca-Freeze
Manufacturer	STC Technologies, Inc	OraSure Technologies, Inc.	Cryosurgery Inc
Type of predicate	primary: technical, dispenser size, cryogen composition; claims; labelling	primary: claims, labelling	secondary: professional use; claims; labelling; buds



8. Device Description

The product is a portable cryosurgery system which is prescription only intended for medical professionals. It is indicated for removal of skin lesions. The product is comprised of a dispenser (canister) containing a cryogen (cryoliquid) which freezes the lesion. It is packaged with a box of single-use foam-sticks (buds). The foam-stick is placed in the front of the dispenser into the opening under the applicator cap. The applicator button is pressed to dispel cryogen on the foam-stick (bud). The foam-stick is applied to the skin lesion for the designated time to freeze the skin lesion.

9. Indications for use

The product is indicated for the treatment of the following skin lesions:

- Verrucae plantaris
- Verrucae Plana
- Verrucae vulgaris
- Mollescum contagiosum
- Skin tags
- Actinic keratosis
- Genital warts
- Lentigo
- Seborrhoeic Keratosis

10. Comparison of technological characteristics with predicate device

The product and the predicate are comprised of a dispenser (canister) with a cryogen used to freeze the skin lesion. The product is packaged with a box of foam-sticks (buds). The predicate and the submission device are used for the same indications, intended purpose and mode of operation; same specifications and same design. Both are for prescription only use.

11. Performance data

The device has been subject to performance testing including

1. Functionality: leakage, temperature probe testing, comparator functionality;
2. Biocompatibility testing to ISO 10993.

Based on the performance testing the product is equivalent to the predicate.

12. Conclusions

Based on the intended use, technical characteristics and performance testing, the device is equivalent to the predicate device.