July 7, 2021

MediLink A/S
Cristina Teixeira
Director for Regulatory Affairs & Quality Assurance
Gammelmosevej 176A
Kgs. Lyngby, 2800
Denmark

Re: K201740
Trade/Device Name: Hydrozid
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: June 8, 2021
Received: June 9, 2021

Dear Cristina Teixeira:

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)*
K201740

Device Name
Hydrozid

Indications for Use *(Describe)*
Hydrozid (also known as R134A or 1,1,1,2-tetrafluoroethane or HFC-134a or HFA-134a or fluorocarbon 134a) is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon (skin tags), molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

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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Traditional 510(k) Summary- Hydrozid®

In accordance with 21 CFR Part 807, Section 807.92, this information serves as a 510(k) summary for Hydrozid®.

Date Prepared: July 6, 2021

Submitted by: MediLink A/S
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Contact Person: Cristina Teixeira
Director of Regulatory Affairs & Quality Assurance
ct@medilink.dk

Proprietary Name: Hydrozid®
Common Name: Portable aerosol cryosurgery device
Classification Name: Unit, Cryosurgical, Accessories
Classification Regulation: 21 CFR 878.4350
Device: Class II
Device Product Code: GEH
Device Panel: General & Plastic Surgery
Predicate Device: Cool Renewal® (K161296)

1. Description of the Device

Hydrozid® is a portable aerosol cryosurgery device intended for the treatment of benign and premalignant skin lesions using a cryogen to freeze cells up to necrosis (cell destruction). The main device component is the aerosol canister containing cryogen spray. The device is provided in a kit containing a canister, application templates and Instructions for Use. The device is used with non-sterile, single-patient application templates which are disposed after use.

The mechanism of action for both Hydrozid® and the predicate device, Cool Renewal®, is based on the principles of cryosurgery (also referred as cryotherapy). Cryosurgery was first described in the 1800s and has since evolved into a well-established therapy within dermatology and other healthcare fields. Cryosurgery is performed using a cryogen to freeze the target tissue temperature to below the level that correlates with cell destruction also known as necrosis. The mechanism of action in cryosurgery are divided into 3 phases: (1) heat transfer, (2) cell death, and (3) inflammation. When the cryogen evaporates, it absorbs heat from its surroundings (heat transfer phase) causing cell destruction (cell death phase) due to:

- Direct effects of freezing on the cells
- Vascular stasis which develops after thawing.

During cryosurgery, both extracellular and intracellular ice formation occur, with fast freezing in the center of the lesion, and slow freezing on the outside border. The loss of blood supply to the treated area eradicates the likelihood of survival of the cells in the frozen tissue (inflammation phase).

2. Indications for Use Statement

Hydrozid® (also known as R134A or 1,1,1,2-tetrafluoroethane or HFC-134a or HFA-134a or fluorocarbon 134a) is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon (skin tags), molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

3. Substantial Equivalence Discussion

The Hydrozid® intended use, indications and clinical application as well as the overall technical characteristics are substantially equivalent to the predicate device. The below table (table 5.3-1) compares the Hydrozid® to the predicate device with respect to intended use, technological characteristics and principles of operation. Differences between Hydrozid® and the predicate device are related to minor material and design elements.

Table 5.3-1: Substantial Equivalence Summary

Device Trade Name	**Hydrozid®**	**Cool Renewal®**	**Significant Differences**
Manufacturer	MediLink A/S	Cool Renewal LCC	N/A
Common Name	Portable aerosol cryosurgery device	Portable aerosol cryosurgery device	Same
Classification name	Unit, Cryosurgical, Accessories	Unit, Cryosurgical, Accessories	Same
Regulation number	21 CFR 878.4350	21 CFR 878.4350	Same
Class	II	II	Same
Device Product Code	GEH	GEH	Same
Device Panel	General & Plastic Surgery.	General & Plastic Surgery.	Same
Sterile	No	No	Same
Indications for Use	Hydrozid® (also known as R134A or 1,1,1,2-tetrafluoroethane or HFC-134a or HFA-134a or fluorocarbon 134a) is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon (skin	1,1,1,2-tetrafluoroethane, Pentafluoroethane, and 1,1,1-trifluoroethane is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon (skin tags), molluscum contagiosum, age spots,	Same

	tags), molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.	dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.	
Intended Users	For professional use only.	For professional use only	Same
Mechanism of Action	Cryosurgery: freeze the target tissue temperature to below the level that correlates with cell destruction (necrosis). When the cryogen evaporates, it absorbs heat from its surroundings causing cell destruction due to:	Cryosurgery: freeze the target tissue temperature to below the level that correlates with cell destruction (necrosis). When the cryogen evaporates, it absorbs heat from its surroundings causing cell destruction due to:	Same

	• Direct effects of freezing on the cells • Vascular stasis which develops after thawing. The mechanism of action in cryosurgery are divided into 3 phases: (1) heat transfer, (2) Cell death, and (3) inflammation.	• Direct effects of freezing on the cells • Vascular stasis which develops after thawing. The mechanism of action in cryosurgery are divided into 3 phases: (1) heat transfer, (2) Cell death, and (3) inflammation.	
Cryogen	R134A: 1,1,1,2-tetrafluoroethane (CAS 354-33-6).	R404A: 1,1,1,2-tetrafluoroethane (CAS 354-33-6); Pentafluoroethane (CAS 420-46-2); 1,1,1- trifluoroethane (CAS 811-97-2)	Similar. Hydrozid® contains only 1 cryogen which is also part of the Cool Renewal® mixture. The cryogen is already used in the predicate device as well as well-established in other medical application (e.g., asthma inhalers and

			skin applications). Furthermore, performance data show Hydrozid® achieves a thermal profile comparable to the predicate device. Hence, no new safety or efficacy concerns are raised.
Freezing time	Transient use; < 1 minute. Specific freeze time determined by the type, size and location of the lesion being treated	Transient use; <1 minute. Specific freeze time determined by the type, size and location of the lesion being treated	Same.
Applicator	Application Templates	Foam Tipped Applicator Plastic Isolation Funnel Foam Tipped Skin Tag Tweezer	Similar. Both devices are supplied with accessories that allow the application for the cryogen

			directly into the patient's skin.

Testing and argumentation rationale were provided to support the equivalence of the Hydrozid® and shows that no new questions of safety and effectiveness have been introduced with this device. The safety and effectiveness of the Hydrozid® are adequately supported by the testing rationale, substantial equivalence information, materials information, and comparison of technical characteristics provided within this premarket notification.

4. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Hydrozid®, and substantial equivalence to the predicate device, a bench test was performed to analyze the thermal profile (surface temperature, duration of the surface temperature and ice-ball geometry and size) of the cryogen R134A and the predicate device cryogen.
The bench test determined that Hydrozid® cryogen performed equivalently to the cryogen of the predicate device.

A second temperature testing performed on Hydrozid® confirmed that the cryogen R134A could reach the minimum desired temperature for cell destruction and vascular stasis in both the minimum and maximum treatment time.

5. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use are equivalent to those of the predicate devices. Portable aerosol cryosurgery devices have been on the market for decades and their clinical safety and efficacy has been established. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

6. Statement of Substantial Equivalence

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the previously cleared

predicate device. While there are minor differences between the Hydrozid® and its predicate device, such differences do not affect the principle of operation or mode of action of the Hydrozid®. Existing differences do not raise new questions regarding safety and effectiveness as compared to the predicate device.

It has been shown in these 510(k) submissions that the minor differences between the Hydrozid® and the predicate device do not raise any questions regarding its safety and effectiveness. The Hydrozid® device is determined to be substantially equivalent to the predicate device, Cool Renewal®.

7. Conclusion

The Hydrozid® device, based on comparison test to the predicate, is substantially equivalent to the predicate device, Cool Renewal®.