May 30, 2023

BIBAWO Medical A/S
Sandra Larsen
Manager of Regulatory Affairs and Quality Assurance
Klintehøj Vænge 6
Birkerød, 3460
Denmark

Re: K221897
Trade/Device Name: Hydrozid Precise
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: April 24, 2023
Received: April 27, 2023

Dear Sandra Larsen:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.30 09:42:22 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221897

Device Name
Hydrozid Precise

Indications for Use *(Describe)*
Hydrozid Precise contains 1,1,1,2-tetrafluoroethane (also known as R134A, HFC-134a, HFA-134a or fluorocarbon 134a) and is to be used for the treatment of verruca (warts), including plantar warts, seborrheic keratosis, actinic keratosis, acrochordon (skin tags), molluscum contagiosum, age spots (lentigo), 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.

510(k) Summary - Hydrozid Precise™

In accordance with 21 CFR Part 807, Section 807.92, this information serves as a 510(k) summary for Hydrozid Precise™ (K221897).

Date Prepared: May 24th, 2023
Submitted by:
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Contact Person:
Sandra Larsen
Manager of Regulatory Affairs & Quality Assurance
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Proprietary Name: Hydrozid Precise™
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: Hydrozid® (K201740) manufactured by BIBAWO Medical A/S is the predicate device.

5.1. Description of the Device

Hydrozid Precise™ is a portable aerosol cryosurgery device intended for the treatment of benign and premalignant skin lesions using a cryogen to freeze cells to induce 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 Precise™ and the predicate device, Hydrozid®, 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).

5.2. Indications for Use Statement

Hydrozid Precise™ contains 1,1,1,2-tetrafluoroethane (also known as R134a, HFC-134a, HFA-134a or fluorocarbon 134a) and is to be used for the treatment of verruca (warts), including plantar warts, seborrheic keratosis, actinic keratosis, acrochordon (skin tags), molluscum contagiosum, age spots (lentigo), dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

5.3. Substantial Equivalence Discussion

The Hydrozid Precise™ intended use, intended users, indications and clinical application as well as the overall technical characteristics are equivalent to the predicate device. The below table (table 5.3-1) compares the Hydrozid Precise™ to the predicate device with respect to intended use, technological characteristics and principles of operation.

Table 5.3-1: Substantial Equivalence Summary

Device Trade Name	**Hydrozid Precise™ Subject Device**	**Hydrozid® Predicate Device**	**Significant Differences**
Manufacturer	BIBAWO Medical A/S	BIBAWO Medical A/S	**Same**
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 Precise™ contains 1,1,1,2-tetrafluoroethane (also known as R134a, HFC-134a, HFA-134a or fluorocarbon 134a) and is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, acrochordon (skin tags), molluscum contagiosum, age spots (lentigo),	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,	**Same**

	dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacanthoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.	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: •Direct effects of freezing on the cells •Vascular stasis which develops after thawing.	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: •Direct effects of freezing on the cells •Vascular stasis which develops after thawing.	**Same**

	The mechanism of action in cryosurgery are divided into 3 phases: (1) heat transfer, (2) Cell death, and (3) inflammation.	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).	R134a: 1,1,1,2-tetrafluoroethane (CAS 354-33-6).	**Same**
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**
Treatment distance	Approximately 1 cm (0.4 in) from the lesion.	2 to 3 cm (0.79 to 1.18 in) from the lesion.	**Similar**
Accessories	Application Templates	Application Templates	**Same**
Technical characteristics Device	Portable cryosurgery device to be applied directly on the indication.	Portable cryosurgery device to be applied directly on the indication.	**Same**
Technical characteristics Spray head design	Spray head has a spray outlet that is 0.1 mm.	Spray head has a spray outlet that is 0.25 mm.	**Similar**
Technical characteristics Spray head design	Consist of a spray head with a fixed tip/tube	Consist of a spray head with a somewhat flexible tip/tube	**Similar**
Technical characteristics Spray head design	Color: black	Color: white	**Similar**

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

5.4. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Hydrozid Precise™, 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) of the cryogen R134a.

The bench test determined that Hydrozid Precise™ performed equivalently to the predicate device Hydrozid®.

The temperature testing performed on Hydrozid Precise™ confirmed that the cryogen R134a was capable of reaching the minimum desired temperature for cell destruction and vascular stasis in both the minimum and maximum treatment time.

5.5. 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. Hydrozid Precise™ does not raise new questions regarding safety and effectiveness as compared to the predicate device.

5.6. Conclusion

The Hydrozid Precise™ device is determined, based on comparison test to the predicate device, to be substantially equivalent to the predicate device, Hydrozid®.