May 6, 2021

The OTC Lab Healthcare B.V.
% Ms. Kathleen Johnson, MSAV
Official Correspondent
Medical Device Approvals, Inc.
104 E. Harrison Ave.
Fairfield, Iowa 52556

Re: K210529
Trade/Device Name: Dr. Yglo Wart Remover
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February 15, 2021
Received: February 23, 2021

Dear Ms. Johnson:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210529

Device Name
Dr. Yglo Wart Remover

Indications for Use *(Describe)*
Dr. Yglo Wart Remover is indicated for the over-the-counter treatment of common warts 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification
510(K) Summary
(As Required by 21 CFR 807.92)

807.92(a)(1)

Sponsor: TheOTCLab Healthcare B.V.
Address: Fred. Roeskestraat 115
1076 EE Amsterdam, The Netherlands
T: 0031 (0)85 4444 202
www.theotclab.com
Sponsor Contact Person: Albert Swane- CEO
The OTC Lab
Fred. Roeskestraat 115
1076 EE Amsterdam
The Netherlands
info@theotclab.com
510(k) Contact Person: Ms. Kathleen Johnson MSAV
Consultant
Medical Device Approvals, Inc.
104 E. Harrison Ave.
Fairfield, IA 52556
kathleen@mdapprovals.com
610-521-9469
Date Prepared: 03-MAY-2021

807.92(a)(2)

Device Trade Name: Dr. Yglo
Proprietary Name: Dr. Yglo Wart Remover
Common Name: OTC Wart Removal System
Classification Name: Cryosurgical units, accessories
Classification Panel: General & Plastic Surgery
Classification Code: GEH
Regulation Number: 21 CFR 878.4350

807.92(a)(3)

Predicate Device:
Substantial equivalence is claimed with the following devices:

Name of Predicate Device	Manufacturer	Predicate Comparison	510(k) Number
Wartie Wart Remover	YouMedical B.V.	Intended use, technology, materials, label	K140314

807.92(a)(4)
Description of the Device:
The Dr. Yglo Wart Remover is effective in the treatment of warts by providing an over the counter cryosurgery product (for the treatment of warts), to be used at home.

Dr. Yglo Wart Remover consists of:

- A pressurized canister filled with 50ml of the compressed liquid gas dimethyl ether.
- A custom application unit used to administer the cold delivered by the cryogen to the wart.
- Instructions for use in which you can read about the product how it works, how to use the product to treat warts, warnings and limitations.

Dr. Yglo Wart Remover contains the following materials:

Location	Material
Cone	POM
Nose Piece	Bronze coated with Nickel
Ring	POM
Can	Aluminum

Dr. Yglo Wart Remover is intended for topical treatment of common and plantar warts, using the following application times, which vary on the basis of the wart diameter:

	WART DIAMETER	TREATMENT TIME
Common warts and plantar warts on toes and arch of foot	Smaller than 3/32 in (2.5mm)	10 seconds
Common warts and plantar warts on toes and arch of foot	3/32 – 3/16 in (2.5 – 5.0 mm)	15 seconds
Common warts and plantar warts on toes and arch of foot	Larger than 3/16 in (5.0mm)	20 seconds
Calloused Plantar warts on heels and balls of feet	All sizes	40 seconds or less

807.92(a)(5)
Indication for Use for the Subject Device:
Dr. Yglo Wart Remover is indicated for over-the-counter treatment of common warts and plantar warts.

Intended Users of the Subject Device:
Dr. Yglo Wart Remover is intended to be used in adults and children 4 years of age and older. Dr. Yglo Wart Remover is to be applied by persons aged 18 years or older.

807.92(a)(6) Technological Characteristics:
Dr. Yglo Wart Remover is a portable cryosurgical system comprised of a canister containing a cryogen and an applicator that applies the cold to the wart to be treated for the over-the-counter treatment of common and plantar warts. The Dr. Yglo Wart Remover employs a metal applicator used as cold retraction vehicle. This allows for pin-pointed accuracy in

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freezing the skin. Finally, the product uses thermal energy removed from skin at the anatomical site of a common wart and/or plantar wart.

807.92(b) Non-Clinical Testing:

1.The following tests were performed on the finished product:

- Stability testing
- Biocompatibility testing
- Usability Study--"Concept and Product Testing with 23 patients for In-Home Use"
- Comparative bench testing between Dr. Yglo Wart Remover and other predicate device using a biological tissue skin test model.

2. Bench testing: Summary

- The following tests were performed on the finished product:
- Comparative performance bench testing with predicate and other competitive devices including freezing performance and skin adherence testing.

The non-clinical and bench testing have supported the safety and efficacy of Dr. Yglo Wart Remover

Substantial Equivalence Information:

	Subject Device Dr. Yglo Wart Remover	**Predicate Device** Wartie Wart Remover
FDA 510(K) number	K210529	K140314
Intended use comparison	OTC treatment of common warts and plantar warts.	OTC treatment of common warts and plantar warts.
indications for use comparison	OTC treatment of common and plantar warts.	OTC treatment of common and plantar warts.
anatomical sites	Topical – Wart.	Topical – Wart.
energy used and/or delivered	Thermal energy removed from skin via a metal interface.	Thermal energy removed from skin via a metal interface.
design	Device requiring activation and application. Metal tip provides pin- pointed accuracy.	Device requiring activation and application. Metal tip provides pin- pointed accuracy.
materials	DME from aerosol can applied to the skin through a metal core via a Nickel tip providing pin- point accuracy.	DME from aerosol can applied to the skin through a metal core via a Nickel tip providing pin- point accuracy.
biocompatibility	Established according to ISO 10993.	Established according to ISO 10993.
Usability	Concept and Product Testing	Unknown

- **Comparison of Technological Characteristics:**

The Dr. Yglo Wart Remover is substantially equivalent to the Wartie Wart Removal System device for the same indications. Both devices are portable cryosurgical systems comprised of a canister containing a cryogen and an applicator that applies the cold to the wart to be treated for the over-the-counter treatment of common and

plantar warts. The Dr. Yglo Wart remover and Wartie Wart Remover employs both a metal applicator. Therefore, Wartie Wart Remover is selected as equivalent product. In fact, the predicate product Wartie Wart Remover has been presented to show the precision freezing performance involved a metal applicator.

This difference in technology has been evaluated in bench testing to determine the equivalence of the products. The equivalent device Wartie Wart Remover has been presented which also uses metal core technology for the cryosurgery of benign skin lesion. Though this product, utilizes a similar technology to cool the metal, it shows that the heat transfer via a metal core is a used and approved technology.

The method of freezing skin via a metal applicator is equivalent to the Wartie Wart Remover predicate device, in that both devices allow for pen-pointed accuracy in freezing the skin. The knowledge of the patient as well as results of the bench testing were taken into consideration.

As mentioned earlier, bench testing has shown the performance of Dr. Yglo Wart Remover to be equivalent with other OTC technologies in terms of safety and efficacy, thereby supporting its OTC status.

The technology employed by Dr. Yglo Wart Remover is similar to its predicate in that the product uses pure DME gas and is applied via a metal applicator, bench testing has shown equivalent performance for safety and efficacy on biological tissue.

- **Summary of Similarities:**

The Dr. Yglo Wart Remover has the following similarities with the Wartie Wart Removal:

- The same intended use and indication for use.
- The same metal-tip applicator
- The same DME gas
- The same warnings and contraindications.
- Available for Over-The-Counter use.
- Destroy common warts and plantar warts by cryoablation.
- Dr. Yglo Wart Remover and Wartie Wart Removal are intended for over- the-counter treatment of common warts and plantar warts.
- Wartie Wart Removal and Dr. Yglo Wart Remover use a cryogen filled into an aerosol can to transform kinetic energy into thermal energy in order to remove a common wart or plantar wart by cryosurgery.
- Dr. Yglo Wart Remover makes use of a secured locking ring in order to assure mechanical safety of the product. A similar feature is also employed by the Wartie Wart Removal.
- In both the predicate device identified above (Wartie Wart Removal System) as well as Dr. Yglo Wart Remover, thermal safety precautions are associated with activation of the aerosol.
- Dr. Yglo Wart Remover, and the predicate device, use thermal energy removed from skin at the anatomical site of a common wart and/or plantar wart.
- The label of the Dr. Yglo Wart Remover has been developed to ensure consumer safety and is equivalent to the predicate devices identified for this purpose.
- The safety and warning statements for the predicate devices and for all the other predicate labeling device are similar.

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- Dr. Yglo Wart Remover employs a metal applicator, which is equivalent to the Wartie Wart Remover predicate device, as both devices allow for pin-pointed accuracy in freezing the skin.

3. Conclusion:

Based on the information presented, it is concluded that the proposed product, Dr. Yglo Wart Remover is safe and effective for its intended use and is substantially equivalent to the predicate device. It can be therefor considered substantially equivalent in intended use, indication for use, safety and affectivity profile, and labeling.