



October 18, 2024

Oystershell NV  
% Phil Triolo  
Founder and Principal Consultant  
Phil Triolo and Associates LC  
86 Skycrest Lane  
Salt Lake City, Utah 84108

Re: K240226  
Trade/Device Name: Pixie Skin Tag  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical Unit And Accessories  
Regulatory Class: Class II  
Product Code: ORE, GEH  
Dated: September 19, 2024  
Received: September 20, 2024

Dear Phil Triolo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**James H.  
Jang -S**

Digitally signed by  
James H. Jang -S  
Date: 2024.10.18  
17:30:13 -04'00'

For  
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

Form Approved: OMB No. 0910-0120

Expiration Date: 07/31/2026

See PRA Statement below.

## Indications for Use

Submission Number (if known)

K240266

Device Name

Pixie Skin Tag

Indications for Use (Describe)

Pixie® Skin Tag is a cryogenic device for home use intended to treat skin tags in persons over the age of 21.

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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|                                                                                  | <b>Pixie Skin Tag</b>                            |                             |

## 510(k) Summary

**Date Prepared:** 18 October 2024

### 1. SUBMITTER

**510(k) Sponsor:** Oystershell NV

**Contact Person:** Phil Triolo, PhD, RAC  
President and Senior Consultant  
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### 2. DEVICE

**Trade/Device Name:** Pixie Skin Tag  
**Common Name:** Over-the-counter cryogenic skin tag remover  
**Classification Name:** Cryosurgical unit and accessories  
**Regulation number:** 21 CFR 878.4350  
**Product Code:** ORE (Cryogenic Skin Tag Removal, OTC)  
**Device Class:** Class II

### 3. PREDICATE DEVICE

**K211099** CryoConcepts Freeze'n Clear Skin Clinic Warts & Tags, Regulation 21 CFR 878.4350, Product Code GEH

### REFERENCE DEVICE

**K172373** Compound W Nitro Freeze, Regulation 21 CFR 878.4350, Product Code GEH

### 4. DEVICE DESCRIPTION

Pixie Skin Tag is a pen-like cryogenic device that utilizes pressurized nitrous oxide (N<sub>2</sub>O, liquefied) to destroy skin tag tissue. The N<sub>2</sub>O is released into a single-use, disposable applicator, cooling the applicator as the result of rapid evaporation. The cooled applicator is briefly contacted with the skin tag while the surrounding tissue is protected by a disposable thermally insulating adhesive bandage. Each Pixie Skin Tag device is supplied in a carton with instructions for use and replacement applicator tips and insulating adhesive bandages.

### 5. INDICATIONS FOR USE

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Pixie® Skin Tag is a cryogenic device for home use intended to treat skin tags in persons over the age of 21.

## 6. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICE

The main difference between the new Pixie Skin Tag and the predicate device is that the new Pixie Skin Tag uses compressed nitrous oxide as the cryogen instead of a combination of dimethyl ether and propane. The evaporation of nitrous oxide results in cooling of the applicator that is contacted with the skin tag during treatments to a lower temperature (-83°C) than the evaporation of the dimethyl ether/propane mixture (-55°C). Contact of the skin tag with the chilled applicator of the new and predicate devices results in cell death due to freezing and blood flow stasis that occurs during thawing of the affected tissue. To protect non-target skin surrounding the skin tag during treatment using the Pixie Skin Tag applicator, thermally insulating bandages are provided for the user to adhere to the skin surrounding the skin tag before treatments. In contrast, the predicate device is provided with tweezers that are used to isolate the skin tag from the surrounding skin to make it easier to contact the skin tag with the applicator without contacting non-target skin.

The Pixie Skin Tag device design and materials are the same as those of the reference Compound W Nitro Freeze Product cleared after FDA review of K172373. The devices differ in the indication for use of the new device to treat skin tags and the inclusion of the single-use, disposable thermally insulating bandages with the new devices.

The following table compares Pixie Skin Tag to the predicate devices with respect to intended use and technological characteristics. This comparison of the devices provides the detailed information that is the basis for the determination of substantial equivalence.

| <b>Substantial Equivalence Table: Comparison of New Device with Legally Marketed Predicate Device</b><br>None of the identified differences raise different questions of safety and effectiveness |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ATTRIBUTE</b>                                                                                                                                                                                  | <b>NEW DEVICE</b><br>Oystershell Pixie Skin Tag (PST)<br><b>K240226</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>PREDICATE DEVICE</b><br>CryoConcepts Freeze'n Clear (FnC)<br>Skin Clinic Warts & Tags<br><b>K211099</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Description                                                                                                                                                                                       | Pixie Skin Tag is a pen-like cryogenic device that utilizes pressurized nitrous oxide (N <sub>2</sub> O, liquefied) to destroy skin tag tissue. The N <sub>2</sub> O is released into a single-use, disposable applicator, cooling the applicator to approximately -83°C as the result of rapid evaporation. The cooled applicator tip is contacted with the skin tag for 20s while the surrounding tissue is protected by a disposable thermally insulating adhesive bandage. The frozen skin tag falls away over time and new epidermis grows in its place. One to three treatments delivered on a 2-week schedule may be delivered (maximum of 3 applications for any one skin tag). | The Freeze 'n Clear Skin Clinic for Warts and Skin Tags is for OTC use and utilizes a combination of dimethyl ether, propane and isobutane (DMEP) delivered from the canister into a single-use, disposable applicator which acts as a reservoir for the cryogenic gas. The gas rapidly evaporates and cools the applicator to approximately -55°C. After a 15-second wait, the applicator is placed against the wart or skin tag for 40 seconds which freezes the targeted tissue. The frozen skin tag or wart falls away over time and new epidermis grows in its place. One to four treatments with intervals of two weeks may be required. |
| Contents                                                                                                                                                                                          | Each Pixie Skin Tag (PST) device is supplied in an outer carton with an instructions for use leaflet and a blister pack containing 4 replacement single-use applicator tips for Pixie 10mL and 9 replacement single-use tips for Pixie 21mL, and a sheet of 10 disposable, single-use insulating adhesive bandages.                                                                                                                                                                                                                                                                                                                                                                     | Freeze 'n Clear Skin Clinic for Warts and Skin Tags is supplied in an outer carton with an instructions for use leaflet, multiple-use actuator, 8 single-use applicator tips, and a multiple-use tweezer.                                                                                                                                                                                                                                                                                                                                                                                                                                      |

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| <b>Substantial Equivalence Table: Comparison of New Device with Legally Marketed Predicate Device</b><br>None of the identified differences raise different questions of safety and effectiveness |                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| Classification                                                                                                                                                                                    | Class II                                                                                                                                                                                                                                                                                                                                                                                                        | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Regulation                                                                                                                                                                                        | 21 CFR 878.4350                                                                                                                                                                                                                                                                                                                                                                                                 | 21 CFR 878.4350                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Name                                                                                                                                                                                              | Unit, Cryosurgical, and Accessories                                                                                                                                                                                                                                                                                                                                                                             | Unit, Cryosurgical, and Accessories                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Panel                                                                                                                                                                                             | General and Plastic Surgery                                                                                                                                                                                                                                                                                                                                                                                     | General and Plastic Surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Product Code                                                                                                                                                                                      | ORE<br>Cryogenic Skin Tag Removal, OTC                                                                                                                                                                                                                                                                                                                                                                          | GEH<br>Cryosurgical unit and accessories                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Intended and Indicated Use                                                                                                                                                                        | Pixie® Skin Tag is a cryogenic device for home use intended to treat skin tags in persons over the age of 21.                                                                                                                                                                                                                                                                                                   | The Freeze 'n Clear Skin Clinic for Warts and Skin Tags product is intended for the OTC treatment of common warts, plantar warts, and skin tags.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Target Population                                                                                                                                                                                 | Persons over the age of 21                                                                                                                                                                                                                                                                                                                                                                                      | No age restriction                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Anatomical Site(s)                                                                                                                                                                                | Only treat skin tags if they are located on the neck, breast, armpits, or underarms via a narrow stalk                                                                                                                                                                                                                                                                                                          | Instructions do not restrict the use of the device to treat skin tags to any specific anatomical locations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Where used                                                                                                                                                                                        | Home (over-the-counter) Use                                                                                                                                                                                                                                                                                                                                                                                     | Home (over-the-counter) Use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Principles of Operation                                                                                                                                                                           | The application of extreme cold removes heat from the targeted skin tag, resulting in freezing and destruction of the tissue.                                                                                                                                                                                                                                                                                   | The application of extreme cold removes heat from the targeted skin tag, resulting in freezing and destruction of the tissue.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Technology                                                                                                                                                                                        | Nitrous Oxide is used to cool an applicator which is applied to the skin tag.<br>The same technology is used by Pixie devices cleared for use to treat warts after FDA review of K172373.                                                                                                                                                                                                                       | DMEP (mixture of dimethyl ether and propane) is used to cool a foam applicator which is applied to the lesion.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Mode of Application                                                                                                                                                                               | User adheres a disposable, thermally insulating bandage to the skin surrounding the skin tag.<br>The user dispenses Nitrous Oxide for 2s into the disposable applicator tip attached to the pen. The applicator is immediately applied to the skin tag for a recommended duration of 20s.<br>The bandage is removed and discarded.<br>Up to 3 treatments may be applied to each skin tag, separated by 2 weeks. | The applicator stick is attached to the actuator. The actuator is pressed into the canister of DMEP (mixture of dimethyl ether and propane) for 3s to 5s to dispense the DMEP and saturate the applicator. The applicator and actuator are removed from the cannister assembly, and the user waits 15s before attempting treatment.<br>To treat the skin tag, the provided tweezers are used to grasp the skin tag and pull it away from its base, exposing the stalk (or stem) of the skin tag. The applicator tip is then applied to the stalk of the skin tag for up to a recommended duration of 40s.<br>Up to 4 treatments may be applied to each skin tag, separated by 2 weeks. |
| Number of treatments                                                                                                                                                                              | Available in 10mL and 21mL sizes, capable of delivering, respectively, 5 and 10 treatments.                                                                                                                                                                                                                                                                                                                     | Available in one size, capable of delivering up to 8 treatments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Flammability                                                                                                                                                                                      | Non-flammable, but will support fire                                                                                                                                                                                                                                                                                                                                                                            | Highly Flammable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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| <b>Substantial Equivalence Table: Comparison of New Device with Legally Marketed Predicate Device</b><br>None of the identified differences raise different questions of safety and effectiveness |                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                             |
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| Storage Conditions and Safety Precautions                                                                                                                                                         | Contents under pressure<br>Never pierce or burn product, even after use.<br>Keep away from fire or flame.<br>Do not smoke while using this product.<br>Do not expose to heat or store at temperatures above 122°F (50°C).<br>Store unused product at room temperature away from heat.<br>Keep out of reach of children. | Do not smoke while using the product.<br>Do not puncture or incinerate canister.<br>Do not expose to heat or store at temperatures above 120°F.<br>Store at room temperature, away from the reach of children, and out of the way of direct sunlight or other heat sources. |
| Disposal                                                                                                                                                                                          | Device is disposable.                                                                                                                                                                                                                                                                                                   | Device is disposable after emptied of cryogen.                                                                                                                                                                                                                              |
| Shelf Life                                                                                                                                                                                        | 3 years (unopened)                                                                                                                                                                                                                                                                                                      | 3 years (unopened)                                                                                                                                                                                                                                                          |
| Sterility                                                                                                                                                                                         | Product is provided non-sterile                                                                                                                                                                                                                                                                                         | Product is provided non-sterile                                                                                                                                                                                                                                             |

## 7. PERFORMANCE EVALUATIONS

### 7.1 Bench Studies

A comparison of the temperatures reached by the new and predicate applicators was conducted and demonstrating that, after dispensing the cryogenic gases into the applicators, the new Pixie Skin Tag applicator reaches and maintains a temperature of approximately -83°C, whereas the predicate applicator reaches a temperature of approximately -33°C, over recommended application durations.

Results of numerous studies demonstrate the ability of PST, after exposure to elevated temperatures or anticipated device misuse, to be activated and dispense N<sub>2</sub>O to the applicators, and, independently, to safely evacuate the pressurized nitrous oxide; and to protect the N<sub>2</sub>O cartridge when the device is dropped.

An analysis of the ability of the thermally insulating bandages to protect the skin from thermal damage during Pixie Skin Tag treatments demonstrated adequate thermal protection.

### 7.2 Animal Studies

A study conducted in rabbits demonstrated that application of PST to healthy rabbit skin resulted in epithelial damage that did not extend deeper than the superficial fascia and evidence of wound healing occurring within 7 days after application.

### 7.3 Clinical Evidence

Results of three usability studies demonstrated that novice laypersons could set up and apply simulated treatments after reading the provided instructions for use.

CE-marked PST devices have been sold in the EU and other countries for several years. Post-market review of complaints reported for CE-marked PST devices sold through the end of 2022 in countries outside the US revealed no reports of serious incidents, and a total of only 5 reported incidents for non-serious events identified as pain, discoloration, blister formation, skin burns, and hypersensitivity reactions. These are known side effects/risks associated with use of

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the device. Further, the low incidence of reported skin burns strongly implies that the insulating bandages are being used properly, and are effective.

Post-market review of complaints reported for the over 3 million devices that have been sold, including over 2 million sold in the US, for reference Pixie devices intended to treat warts, revealed only one serious event. The very low and acceptable rates of reported non-serious events, all of which are communicated to end users in the instructions for use, were 0.019% in 2021 and 0.012% in 2022 (based on an assumption that 50% of devices sold were used).

## 8. SOFTWARE

No software is employed in the Pixie Skin Tag device.

## 9. BIOCOMPATIBILITY

Pixie Skin Tag pen and applicator components and their processing are the same as those of the reference predicate device which is intended for the same user (patient) contact. Therefore, the biological and toxicological risks associated with the Pixie Skin Tag applicator assembly are the same as the reference predicate device and are low and acceptable.

The thermally insulating bandages make direct contact with intact skin. Results of in-vitro cytotoxicity (MEM Elution), sensitization, and intracutaneous injection studies, conducted in accordance with ISO 10993-5, ISO 10993-10, and ISO 10993-10, respectively, met all acceptance criteria, demonstrating low and acceptable biological and toxicological risks.

## 10. STERILIZATION

Neither the new Pixie Skin Tag nor the predicate device is sterilized.

## 11. STANDARDS

The following standards were referenced in this 510k to support substantial equivalence:

- [ISO 10993-1](#)
- [ISO 10993-5](#)
- [ISO 10993-10](#)
- [ISO 10993-12](#)
- [IEC 62366](#)
- [ISO 14971](#)
- [ISO 14155](#)
- [ISO 20417](#)

## 12. CONCLUSION

The results of bench, pre-clinical, and usability studies and comparisons with the predicate device provide the evidence needed to find that Oystershell's new Pixie Skin Tag devices are substantially equivalent to the predicate CryoConcepts Freeze'n Clear Skin Clinic Warts & Tags.