**510(K) Summary**

**CryoTouch™**

**PREMARKET NOTIFICATION 510(K) SUMMARY**

I. SUBMITTER

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II. DEVICE

Name of Device: CryoTouch™

Usual Name – Cryosurgical unit and accessories
Classification Name – General & Plastic Surgery
Regulatory Class: GEH
Product Code: GEH

III. PREDICATE DEVICE

Verruca Freeze K982506

IV. DEVICE DESCRIPTION

The CryoTouch™ device gently dispenses cryogen gas into an applicator or a uniquely designed cone. The applicator or cone is then used to apply the extreme cold to the lesion being treated to effect cryosurgical treatment.

V. INDICATIONS FOR USE

The CryoTouch™ is intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures.

The list below shows examples of the types of lesions that may be treated:

- Verruca (warts)
- Plantar warts
- Seborrheic Keratoses
- Actinic Keratoses
- Achrochordon

- Molluscum Contagiosum
- Age Spots
- Dermafibroma
- Small Keloids
- Granuloma Annulare
- Porokeratosis Plantaris
- Angiomas
- Lentigo Maligna
- Keratoacanthoma
- Basal Cell Carcinomas
- Bowen's Disease
- Lentigo Discrete
- Chondrodermatitis
- Epithelial Nevus
- Leukoplakia
- Granuloma Pyogenicum
- Kaposi's Sarcoma
- Pyogenic Granuloma

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of the technological characteristics for the CryoTouch™ versus the Verruca Freeze predicate is provided in the following table.

| Technological Characteristics | Verruca Freeze K982506 | CryoTouch |
|---|---|---|
| **-Intended Use** | Intended Use: Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane is to be used for the treatment of: -verruca (warts), including plantar warts, -seborrheic keratoses, -actinic keratoses, -achrochordon (skin tags), -molluscum contagiosum, -age spots, -dermafibroma, -small keloids, | Intended Use: Pentafluoroethane and Difluoromethane is to be used for the treatment of: -verruca (warts), including plantar warts, -seborrheic keratoses, -actinic keratoses, -achrochordon (skin tags), -molluscum contagiosum, -age spots, -dermafibroma, -small keloids, -granuloma annulare, |

| Technological Characteristics | Verruca Freeze K982506 | CryoTouch |
|---|---|---|
| | -granuloma<br>-annulare,<br>-porokeratosis plantaris,<br>-angiomas,<br>-lentigo maligna,<br>-keratoacanthoma,<br>-basal cell carcinoma,<br>-bowen's disease,<br>-lentigo discrete,<br>-chondrodermatitis,<br>-epithelial nevus,<br>-leukoplakia,<br>-granuloma pyogenicum,<br>-kaposi's sarcoma,<br>-pyogenic granuloma[1] | -porokeratosis plantaris,<br>-angiomas,<br>-lentigo maligna,<br>-keratoacanthoma,<br>- basal cell carcinoma,<br>-bowen's disease,<br>-lentigo discrete,<br>-chondrodermatitis,<br>-epithelial nevus,<br>- leukoplakia,<br>-granuloma pyogenicum,<br>-kaposi's sarcoma,<br>-pyogenic granuloma |
| **-Cryogen Characteristics** | Mixture of Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane | Mixture of Pentafluoroethane and Difluoromethane |
| **Cryogen Gas Boiling Point** | -48(°C) | -52(°C) |
| **-Materials** | -Aerosol canister containing cryogen<br>-Foam tipped applicators<br>-Plastic cones of various sizes | -Aerosol canister containing cryogen<br>-Cellulose applicators<br>-Cones with various size adaptors |
| **-Mode of Use** | Uses both cones and applicators to apply cryogen to the skin | Uses both cones and applicator to apply cryogen to the skin |
| **-Mechanism of action** | A mixture of Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane is delivered to the skin either by spraying through the cone or spraying into a bud which contacts the skin. The boiling point | A mixture of Pentafluoroethane and Difluoromethane is delivered to the skin either by spraying through the cone or spraying into an applicator which contacts the skin. The |

| Technological Characteristics | Verruca Freeze K982506 | CryoTouch |
|---|---|---|
| | of the gas mixture is -48°C [2] | boiling point of the gas mixture is -52°C [3] |
| **-Storage Conditions** | Store in a room where the temperature does not exceed 120°F and the canister is kept out of direct sunlight [2] | Canisters should be stored at room temperature and should not be subjected to temperatures over 125°F [3] |
| **-Safety** | -Non-Flammable under use conditions -MSDS Provided | -Non-Flammable under use conditions -MSDS Provided |
| **-Treatment Procedure** | Spray the cryogen either onto the bud to saturate it and then place the bud directly onto the lesion or spray the cryogen through the cone onto the lesion | Spray the cryogen either into the applicator to saturate it and then place the applicator directly onto the lesion or spray the cryogen through the attached cone onto the lesion |
| **-Operation** | Gas dispense initiated by applying pressure to the trigger and stopped by releasing the trigger. | Gas dispense initiated by applying pressure to the trigger and stopped by releasing the trigger. |
| **-Disposal** | Entire unit is disposable after emptied of cryogen. The cones are reusable, and the buds are disposable | Entire unit is disposable after emptied of cryogen. The cone is reusable. The cone adapters and applicators are disposable |
| **-Defined Operators** | Licensed Medical Professionals | Licensed Practitioners |
| **-Service/Repair** | None | None |

VII. PERFORMANCE DATA

Cryosurgery works to destroy target lesions through applied extreme cold. When sufficient heat has been removed from the treated spot, the tissue is destroyed through cell lysis and vascular stasis.

The CryoTouch™ device utilizes a mixture of Pentafluoroethane and Difluoromethane while the predicate Verruca Freeze utilizes a mixture of Tetrafluoroethane, Pentafluoroethane, and Trifluoroethane. All of these gases are within the same family of refrigerants and reach similar temperatures.

Bench testing in this submission focused on demonstrating the equivalency of temperatures over their treatment times while using cone or applicators from the CryoTouch™ and Verruca Freeze.

A second bench test also used the CryoTouch™ and Verruca Freeze, comparing each device and its ability to destroy red blood cells immobilized in agar.

VIII. CONCLUSIONS

Various types and mixtures of refrigerants are well-established and used in cryosurgical products to achieve sufficiently low temperatures to effect tissue destruction through extreme cold temperatures. The comparison bench testing of the CryoTouch ™ to Verruca Freeze shows that the temperatures attained are sufficient for cryosurgery. The data, therefore, supports the substantial equivalence between CryoTouch™ and the predicate.