**510(k) Summary**

**CryoLab®**

**510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

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II. DEVICE

Name of Device: CryoLab®
Classification Name: Unit, Cryosurgical, Accessories
Regulation Number: 21 CFR 878.4350
Regulatory Class: Class II
Product Code: GEH

III. PREDICATE DEVICE

Primary Predicate Manufacturer: CryoConcepts
Primary Predicate Trade Name: CryOmega-Flexx
Primary Predicate 510(k): K172769

Secondary Predicate Manufacturer: Erbe
Primary Predicate Trade Name: ERBOKRYO CA
Secondary Predicate 510(k): K934261

IV. DEVICE DESCRIPTION

The CryoLab® device is designed to electronically control a timed dispense of cryogen gas when actuated. The device contains no software and uses a cylinder of nitrous oxide or carbon dioxide. Licensed Practitioners can dispense the gas for use in procedures requiring the surgical destruction of target tissue using the extreme cold of nitrous oxide, $N_2O$ (-89°C) or carbon dioxide, $CO_2$ (-79°).

V. INDICATIONS FOR USE

The CryoLab® 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:

- Molluscum Contagiosum
- Skin Tags
- Actinic Keratosis
- Lentigo
- Verruca Plana
- Verruca Vulgaris
- Verruca Plantaris
- Genital Lesions
- Seborrheic Keratosis

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The following characteristics were compared between the subject device and the predicate devices in order to demonstrate substantial equivalence.

A summary of the technological characteristics for the CryoLab® versus the CryOmega Flexx and the ERBOKRYO CA predicates is provided in the following table:

- Intended Use
- Cryogen Characteristics
- Materials
- Mode of Use
- Mechanism of Action
- Storage Conditions
- Safety
- Electrical Safety
- Gas Cartridge Safety
- Treatment Procedure
- Operation
- Disposal
- Defined Operators
- Service / Repair

| Technological Characteristics | CryOmega Flexx K172769 | Erbe ERBOKRYO CA K934261 | CryoLab® |
|---|---|---|---|
| **Intended Use Statement** | Intended Use: The CryOmega Flexx utilizes a reusable spray applicator and disposable gas cartridges intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. | Intended Use: The ERBE ERBOKRYO CA Cryosurgical Unit and Accessories are intended for devitalization (destruction) of tissue during surgical procedures by the application of extreme cold and for removal of foreign bodies, mucous plugs, necrotic tissue, and tissue biopsy by cryoadhesion. | Intended Use: The **CryoLab®** utilizes a reusable spray applicator and disposable gas cylinder intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. |
| **Cryogen Characteristics** | Nitrous Oxide, $N_2O$ 16g or 25g cylinders with internal valve | Nitrous Oxide, $N_2O$ or Carbon Dioxide, $CO_2$ Cylinder | Nitrous Oxide, $N_2O$ or Carbon Dioxide, $CO_2$ Cylinder with internal valve |
| **Materials** | Housing: Metal/Glass<br>Spray Tip Applicators<br>Gas Cylinder: Metal | ERBOKRYO CA Cryosurgical Unit<br>Pin Index Connectors for $CO_2$ and $N_2O$<br>Flexible Hose<br>Flexible Cryo Probe<br>Connecting Adaptor<br>Footswitch.<br>Gas Cylinder: Metal | Housing: Plastic<br>Filter: Metal<br>O-rings: Butadiene-rubber<br>Gas Cylinder: Metal |
| **Mode of Use** | Apply Spray Topically | Apply using cooled contact probe | Apply Spray Topically |
| **Mechanism of Action** | Cryogen, $N_2O$, is delivered to the treatment site to effect cellular destruction [3] | Cryogen, $N_2O$ or $CO_2$ cools contact probe which is applied to the treatment site to effect cellular destruction | Cryogen, $N_2O$ or $CO_2$, is delivered to the treatment site to effect cellular destruction. |
| **Storage Conditions** | <50°C | Not Defined | <50°C |
| **Safety** | Complies with ASTM: F882-84 (96) for Cryosurgical Medical Instruments | Has an added internal filter at the gas safety outlet in order to comply with the ASTM standard | Complies with ASTM: F882-84 (96) for Cryosurgical Medical Instruments |
| **Electrical Safety** | Not Applicable | Compliance with IEC 60601-1 | Compliance with IEC 60601-1 |
| **Gas Cartridge Safety** | Cartridge is unscrewed from the unit and replaced when empty. | External cryogen cylinder is fitted with a regulator | Cylinder is unscrewed from the unit and replaced when empty. Cylinder |

| Technological Characteristics | CryOmega Flexx K172769 | Erbe ERBOKRYO CA K934261 | CryoLab® |
|---|---|---|---|
| | Cartridge may be removed between uses | | may be removed between uses |
| **Treatment Procedure** | Freezing of target tissue by open spray. Manual Valve control during gas dispense | Pressurized gas causes a temperature drop in the cryoprobe tip that, in turn, is applied to the target tissue to destroy or remove tissue. The unit has an analog switch and basic time display. | Freezing of target tissue by open spray. Electronically controlled gas dispense increases accuracy of timed spray. |
| **Operation** | Gas dispense control using actuator lever. Spray controlled by on/off actuator | A pedal footswitch is used to start or stop the flow of cryogen to the cryoprobe tip | Gas dispense controlled using electronically timed dispense which is actuated using button on the device wand. |
| **Disposal of Cylinder** | Applicator Spray Unit is reusable with replaceable gas cylinder | Applicator Unit is reusable with replaceable gas cylinder | Applicator Spray Unit is reusable with replaceable gas cylinder |
| **Defined Operators** | Licensed Practitioner | Licensed Practitioner | Licensed Practitioner |
| **Service/Repair** | Return to Manufacturer | Return to Manufacturer | Return to Manufacturer |

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1. **Bench Testing**
   The use of either liquid Nitrous Oxide or Carbon Dioxide to effect cellular destruction in clinical tests is well established in the literature. Therefore, bench testing data is provided in support of the substantial equivalence determination.

   The CryoLab® device utilizes either liquid nitrous oxide or carbon dioxide while the predicate CryOmega Flexx and ErbeKryo CA utilize liquid nitrous oxide and/or carbon dioxide.

   Bench testing in this submission focused on demonstrating the equivalency of gas dispensed per unit of time and the temperature attained using open sprays comparing the CryOmega Flexx and CryoLab® with Nitrous Oxide. The ErbeKryo CA is a contact freeze device and not directly comparable in the bench tests performed. For this reason, the CryoClear device, which has a similar design and open spray mechanism as the CryOmega Flexx, was compared to the CryoLab® with Carbon Dioxide.

A second bench test also used the CryOmega Flexx and CryoLab® comparing a spray of liquid nitrous oxide from each device and its ability to destroy red blood cells immobilized in agar.

Both bench tests adequately demonstrate the equivalent delivery of cryogen gas when comparing the CryOmega Flexx and CryoLab® devices. The procedures and results can be found in Section 17, Performance Bench Testing of this submissions.

2. **Biocompatibility Testing**
   Not Applicable: the cryogen gas is the only patient contacting component.

3. **Sterility Testing**
   Not Applicable: the cryogen gas is the only patient contacting component.

4. **Electrical Safety and Electromagnetic Compatibility**
   CryoConcepts has conducted testing on the CryoLab® to verify compliance with IEC 60601-1 IEC 60601-1:2005 3ed. +A1:2012 and IEC 60601-1-2:2015. Compliance to the consensus standard 19-4 has been declared in Section 8 of this report, entitled Declaration of Conformity and Summary Reports.

5. **Software Verification and Validation**
   Not Applicable: no software.

6. **Performance Testing - Animal**
   Animal performance testing was not required to demonstrate safety and effectiveness of the device

7. **Performance Testing - Clinical**
   Clinical testing was not required to demonstrate the safety and effectiveness of the device. Instead, substantial equivalence is based upon benchtop performance testing.

8. **Human Factors Testing**

   Human Factors testing was performed as part of the performance testing. A usability engineering evaluation demonstrating the medical device design meets its intended purpose and incorporates human factors in engineering to ensure the product is safe and easy to use.

VIII. CONCLUSIONS

Both Nitrous Oxide and Carbon Dioxide are well established as cryogen gases used in cryosurgical products. The comparison bench testing of the CryOmega Flexx to the **CryoLab®** show that the temperatures attained and amount dispensed are substantially the same when Nitrous oxide is used in the **CryoLab®**. Another device called CryoClear, was used to show that the temperatures attained and the amount dispensed are substantially the same when Carbon Dioxide is used in the **CryoLab®**. The **CryoLab®** is as safe and effective as the predicate devices. The **CryoLab®** has the same principal of action and intended use in regard to the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. The data therefore supports the substantial equivalence between the **CryoLab®** and the Predicates.