

2.1 510(K) Summary

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Device Description

The current ENDOcare CRYOcare™ Cryosurgical System is a cryosurgical system that consists of a control unit and eight cryoprobes. The Cryosurgical System also incorporates independent thermocouple inputs to monitor temperatures from standard T-type needle thermocouples. The system is compact and operates off of standard 110 VAC wall power. The control units for the 2 and 5-probe models will have the same performance characteristics as the 8-probe model. The only difference will be in the outer case which will be smaller and more cost effective to meet the needs of different customers.

At the heart of the ENDOcare CRYOcare™ Cryosurgical System is the Cryoprobe. The Cryoprobes limit the extreme cold zone to a small active area at the tip, which results in an overall more efficient surgical tool. The probes are supplied sterile and individually packaged. The probes used for the 2-probe and 5-probe output configurations are exactly the same as those for the 8-probe output configuration. The ENDOcare Cryoprobe is a single use cryostat. Cryostats have been used as refrigerant devices for the past one hundred years. The Cryoprobe has no moving parts and is made of standard surgical stainless steel. The ENDOcare Cryoprobe is small enough in diameter to used medically, yet generates enough cooling capacity to effectively ablate tissue

Substantial Equivalence Support

The ENDOcare CRYOcare™ Cryotherapy System is designed for use in general surgery, dermatology, neurology, thoracic surgery, ENT, gynecology, oncology, proctology and urology for the ablation of tissue, including liver metastases, skin lesions, warts and removal of prostate tissue. The current ENDOcare CRYOcare™ Cryotherapy System includes an 8-probe output model which was originally determined to be substantially equivalent on January 19, 1995 (reference K942299). The system will also be marketed in smaller, more cost effective models that utilize less probes. In addition to the 8-probe output model, ENDOcare will market a 2-probe output and a 5-probe output model. The additional models are substantially equivalent to the previously cleared device. The performance characteristics and technology will remain the same. The primary difference is that the number of probes will be less and the control units will be smaller to meet the different needs of customers.

Sterilization Methodology

The following sterilization information is applicable to the Cryoprobes only. Sterilization validation will be conducted utilizing an overkill method based on the recommendations in the current American Association for the Advancement of Medical Instrumentation (ANSI/AAMI/ISO 11135-1994) Guideline for Industrial Ethylene Oxide.

Sterilization of Medical Devices. A minimum Sterility Assurance Level (SAL) of 10^{-6} will be achieved. Sterile barrier packaging will consist of standard disposable medical device packaging containing a plastic film and a coated paper side. This is the same sterile barrier packaging that is used with the 8-Probe model. Maximum levels of EtO residuals will not exceed:

- 25 ppm for ethylene oxide**
- 25 ppm for ethylene chlorohydrin**
- 250 ppm for ethylene glycol**