

FEB 25 1997

Section 2.0 - SMDA 1990 Requirements

2.1 510(k) Summary

Device Description

The ENDOcare Urethral Warming System consists of a balloon catheter, PVC tubing set, heater/heater stand and roller pump. The urethral catheter consists of a polyurethane shaft with a polyester balloon. The system provides a steady flow of warm water or saline from an I.V. bag to the catheter in order to transfer heat to the urethral tissue during urological cryosurgery procedures. The catheter has an inlet port which allows the warm water or saline to flow into the balloon, warming the surrounding urethral tissue. An outlet port allows the water or saline to exit the catheter and return to the I.V. bag. The water or saline in the I.V. bag is maintained at a set temperature of 37.5°C by the heater. A shut-off feature prevents the temperature from exceeding 42°C. The water or saline is circulated by a roller pump from the catheter to the I.V. bag in a closed circuit.

Biocompatibility

The biocompatibility requirements were determined through use of the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The urethral warming catheter is the only component of the system which has patient contact. The catheter has the same material, manufacturing process, chemical composition, body contact and sterilization method as the marketed catheter. Therefore, per the FDA matrix the biocompatibility requirements were met and no additional testing was performed.

Substantial Equivalence Support

The ENDOcare CRYOcare™ Cryosurgical System is designed for use in general surgery, dermatology, neurology, thoracic surgery, ENT, gynecology, oncology, protology and urology for the ablation and destruction of tissue by the application of extreme cold. The ENDOcare Urethral Warming System is an accessory to the cryosurgical system and is indicated to transfer heat to the urethral tissue during urological cryosurgery procedures using the ENDOcare CRYOcare™ Cryosurgical System. The Urethral Warming System is substantially equivalent to the Cryomedical Sciences, Inc. Urethral Warmer which was determined to be substantially equivalent on October 24, 1995 (reference K952895). The ENDOcare Urethral Warming system consists of a balloon catheter, tubing, heater and roller pump which are substantially equivalent to the marketed device. The catheter is the only component with direct patient contact and it is manufactured with the same materials as the marketed device.

In Vitro Testing

Bench testing was conducted to compare the functional performance of the ENDOcare Urethral Warming System to the Cryomedical Sciences Urethral Warmer. At a set point temperature of 37.5°C, the performance of the two systems was determined to be equivalent.

Sterilization Methodology

Ethylene oxide will be utilized to sterilize the catheter and tubing set. Sterilization validation will be based on the recommendations in the current AAMI (American Association for the Advancement of Medical Instrumentation) 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 type of sterile barrier packaging that is used with the marketed device. Maximum levels of EtO residuals will not exceed:

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

The heat exchanger cassette will be received sterile from the supplier. This component is gamma sterilized. Sterilization validation was based on the recommendations of the current AAMI Guideline for Gamma Radiation to achieve a minimum Sterility Assurance Level (SAL) of 10^{-6} .