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Section 2.0 - SMDA 1990 Requirements

K965118

2.1 510(k) Summary

Device Description

The ENDOcare Electrosurgical Electrodes are accessories that fit commercially available resectoscopes, cystoscopes, laproscopes and hysteroscopes, pencil grips and pistol grips. Each model has a different configuration which offers the surgeon a variety of tissue interaction tips depending on the specific surgical application.

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 ENDOcare Electrosurgical Electrode has the same material, manufacturing process, chemical composition, body contact and sterilization method as the currently marketed electrode. Therefore, per the FDA matrix, the biocompatibility requirements were met and no additional testing was performed.

Substantial Equivalence Support

The ENDOcare Electrosurgical Electrodes are designed for use in general surgery, urology, gynecology and orthopedics for cutting, coagulation, resection and vaporization of tissue including BPH (Benign Prostatic Hyperplasia), tumors, fibroids, cysts and obstructive tissue. The ENDOcare Electrosurgical Electrodes are substantially equivalent to the ENDOcare Monopolar Electrodes (reference K952587) which were found to be substantially equivalent to the Unimed Electrodes (reference K944540 and K945191) on July 17, 1995.

Sterilization Methodology

Two methods of sterilization may be employed for this device:

(1) Ethylene Oxide

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 pouch containing a plastic film and a coated paper side. This is the same type of sterile barrier packaging that is used with the currently 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

(2) Gamma Radiation

Sterilization will be based on the recommendations in the current American Association for the Advancement of Medical Instrumentation (ANSI/AAMI/ISO 11137-1994) Guideline for the Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization. A minimum Sterility Assurance Level (SAL) of 10^{-6} will be achieved. Sterile barrier packaging will consist of standard disposable pouch containing a plastic film and a coated paper side. This is the same type of sterile barrier packaging that is used with the currently marketed device.