

11
K960413

APR - 4 1996

Attachment 14
510(k) Summary Statement for the
Coherent SlimLine Single Lumen Aspiration Needle Set

I. General Information

Submitter: Coherent Medical Group
3270 West Bayshore Road
Palo Alto, CA 94303

Contact Person: Anne C. Worden

Summary Preparation Date: January 25, 1996

II. Names

Device Names: Coherent SlimLine Single Lumen Aspiration Needle Set.

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories).

III. Predicate Devices

- Suction/Irrigation Probe (with long adapter/sizing sheath, short adapter and gasket) Accessory Kit marketed by Coherent Medical, Inc. (K923575, K902990)
- LASE Surgical Kit (Model 1100 Discectomy Decompression Kit) manufactured by Clarus Medical Systems, Inc. (K913136)

IV. Product Description

The Coherent SlimLine Single Lumen Aspiration Needle Set and associated accessories are intended to be used to help deliver laser light energy from the Coherent SlimLine Family of fiber optic fibers used with the Coherent VersaPulse Family of Ho:YAG and Ho:YAG/Nd:YAG surgical lasers for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue and urinary calculi (including steinstrasse) in a variety of medical specialties.

Coherent SlimLine Single Lumen Aspiration Needle Set are comprised of the following main components:

- the handpiece assembly (with optical fiber locking nut and locking nut O-ring);
- the optical fiber stop;
- aspiration needles (straight and curved needles of various lengths);
- aspiration needle locking nut (with locking nut O-ring);
- positioning trocars; and
- a sterilization tray

The SlimLine Single Lumen Aspiration Needles are provided as non-sterile, ready to be sterilized devices that are either available individually or as a set of three aspiration needles in a sterilization tray.

V. Indications for Use

The Coherent SlimLine Single Lumen Aspiration Needle Set and the Delivery Accessories that are used with them to deliver light energy are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); arthroscopy (knee surgery); and open and endoscopic general surgery, and for aspiration and/or irrigation of fluid and/or surgical debris.

VI. Rationale for Substantial Equivalence

The Coherent SlimLine Single Lumen Aspiration Needle Set and their delivery device accessories share the same indications for use, similar design features, components and materials, and therefore are substantially equivalent to the Suction/Irrigation Probe Accessory Kit marketed by Coherent Medical, Inc. (K923575, K902990), and to the cannulas, trocar, and trephine components included in the LASE Surgical Kit manufactured by Clarus Medical Systems, Inc. (K913136).

VII. Safety and Effectiveness Information

Physical testing was conducted to demonstrate performance of the Coherent SlimLine Single Lumen Aspiration Needle Set in accordance with product specifications. The component materials with expected and potential patient contact were tested to demonstrate acceptable biocompatibility. Sterility testing was conducted to validate that the SlimLine Single Lumen Aspiration Needles attain a sterility assurance level (SAL) of 10^{-6} when sterilized in accordance with the directions provided in the Instruction Guide.

VIII. Conclusion

The Coherent SlimLine Single Lumen Aspiration Needle Set was found to be substantially equivalent to the cannula, trocar and trephine components provided in the LASE Surgical Kit manufactured by Clarus Medical Systems, Inc. The Coherent SlimLine Single Lumen Aspiration Needle Set shares the same indications for use, similar design features, and similar functional features as the currently marketed Coherent Irrigation/Suction Probe Accessory Kit, and the cannula, trocar and trephine components provided in the currently marketed LASE Surgical Kit. The physical test results demonstrated that the Coherent SlimLine Single Lumen Aspiration Needle Set have acceptable performance characteristics.