K965045

MAY - 5 1997

p 1 of 2

Appendix A 510(k) Summary of Safety and Effectiveness

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The TRISTAR™ LP Trocar with Low Profile Threaded Sleeve consists of two main sub-assemblies: an obturator sub-assembly and a sleeve sub-assembly.

The obturator consists of a sharp pyramidal tip and a spring loaded safety shield. The safety shield is designed to cover the pyramidal tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered.

The sleeve subassembly has an inner gasket seal and an outer gasket seal to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through cannula during a surgical procedure. Integral threads along the outside diameter of the cannula portion of the sleeve provide a retention mechanism to stabilize the sleeve in tissue.

The TRISTAR™ LP Trocar with Low Profile Threaded Sleeve shall be provided in a variety of sizes from 3mm to 12mm in diameter and 65mm to 150mm in length.

This device is designed to create secondary trocar sites and is labeled to be used only under direct visualization of the insertion site.

Intended use

The intended use of the New Device is to establish a path of entry for minimally invasive instruments. The instrument is intended for creating secondary ports under direct visualization.

Indications statement

The TRISTAR™ LP Trocar with Low Profile Threaded Sleeve has application in thoracic, general, gynecologic, or other minimally invasive surgical procedures to establish a path of entry for minimally invasive instruments. The instrument is intended for insertion under direct visualization for secondary port locations.

Continued on next page

K 965045
P 2 of 2

Appendix A 510(k) Summary of Safety and Effectiveness, Continued

Technological characteristics	The technological characteristics of the New Device are the same as the Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device in mating the obturator with the sleeve, insertion into the operative cavity, removal of the obturator from the sleeve, security of the sleeve in tissue, and maintenance of pneumoperitoneum of the operative space.
Conclusion	Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.
Contact	Ivan S. Placko Project Manager Regulatory Affairs Department Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
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