ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

JAN 8 1997

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4545 CREEK ROAD
CINCINNATI, OH 45242-2839

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 (TRADE NAME) Non-shielded Surgical Trocar consists of two main sub-assemblies: a non-shielded obturator sub-assembly and the sleeve sub-assembly.

The non-shielded obturator sub-assembly is designed with a protective sheath to cover the flat blade. This protective sheath protects the gaskets on the sleeve assembly when the obturator and sleeve are mated together for insertion into the operative cavity. When the sleeve and obturator are properly engaged, the protective sheath is retracted so that the blade is exposed when it extends from the trocar sleeve.

An inner and outer gasket seals to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through cannula during a surgical procedure.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 (TRADE NAME) Non-shielded Surgical Trocar shall be provided in a variety of sizes from 3mm to 12mm in diameter and 75mm 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

To establish a path of entry for minimally invasive instruments. The instrument is intended for creating secondary ports under direct visualization.

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510(k) Summary of Safety and Effectiveness, Continued

Indications statement	The (TRADE NAME) Non-shielded Surgical Trocar with 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.
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.
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Date	December 9, 1996