

10. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

K 970826

A. Submitter Information

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B. Device Identification

Common/Usual Name: Manual Detachable Surgical Instruments  
Proprietary Name: "Selecta-Tip" Laparoscopic Scissors Tips

C. Identification of Predicate Device(s)

The "Selecta-Tip" Laparoscopic Instruments are substantially equivalent to their predicate, "Re-New (K962119), previously cleared and currently marketed.

D. Device Description

The "Selecta-Tip" Laparoscopic Scissors are surgical blades used to cut and dissect various abdominal tissue for use in endoscopic, including laparoscopic, surgical procedures. The product line includes reusable common handles that can be easily attached and detached from a series of reusable tips.

The tip assembly is designed with a proprietary single thread and ball system, which permits simple and reliable attachment and detachment of the desired tip to the shaft of the handle/shaft component. Scissors tip configurations include:

- Metzenbaum,
- Mini,
- Hook,
- Endocut, and
- Micro.

E. Substantial Equivalence

The technical characteristics of the "Selecta-Tip" Laparoscopic scissors tips are almost identical to those of the Microline "Re-New". Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the "Selecta-Tip" relative to its predicate.

"Selecta-Tip" Laparoscopic scissors tips are intended for use to cut and dissect various abdominal tissue in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula.

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