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SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

**510(k) Summary of Safety and Effectiveness**

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.

NEW DEVICE NAME: ETHICON ENDOSUTURE System

PREDICATE DEVICE NAME(S): ENDOLOOP Ligature with Introducer, Pre-Tied Loop Suture Cannula.

510(K) SUMMARY

**Device Description**

ETHICON ENDOSUTURE System is comprised of two (2) parts, the ENDOSUTURE System ENDO-HOLDER Cannula Knot Pusher and the ENDOSUTURE System suture. Each is available separately for assembly at the surgical site. The ENDOSUTURE System ENDO-HOLDER is a one-piece stainless steel device designed to accept the ENDOSUTURE System suture. The ENDOSUTURE System ENDO-HOLDER is provided non-sterile for sterilization before initial use and is reusable. ENDOSUTURE System sutures are conventional sutures, the same suture materials available by ETHICON, Inc. allowed to be marketed by FDA. The ENDOSUTURE System suture is configured in either a loop or pre-tied with needle or a suture strand with needle. Pre-threaded to each ENDOSUTURE System suture is a plastic passer and slide component that is designed for loading the suture in the ENDOSUTURE System ENDO-HOLDER.

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| **Intended Use** | Introduces sutures and facilitates knot tying of surgical sutures in endoscopic (videoscopic) procedures. |
| **Indications Statement** | Introduces sutures and facilitates knot tying of surgical sutures in endoscopic (videoscopic) procedures. |
| **Technological Characteristics** | The new device is technologically like the predicate device (except, i.e., a cannula with a surgical suture). Differences do not raise new questions of safety and effectiveness. |
| **Performance Data** | Benchtop evaluations were conducted on the sutures used in the ENDOSUTURE System to assess USP characteristics (diameter, knot tensile strength and needle pull-off). Comparative benchtop functionality testing was conducted to assess knot security following knot placement. Nonclinical laboratory testing was conducted to determine breaking strength retention. |
| **Conclusions** | 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** | August 21, 1996 |