

K960476

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 Bipolar Scissors and Accessory Cable

PREDICATE DEVICE NAME: EVERSHEARS II Bipolar Laparoscopic Scissors

510(K) SUMMARY

Device Description

The ETHICON Bipolar Scissors are available in various standard sizes and shapes similar to conventional surgical scissors. These scissors can be connected to the bipolar output mode on electrosurgical generators to facilitate dissection, transection, and bipolar coagulation.

The ETHICON Bipolar Scissors are designed for use with the ETHICON Bipolar Cable (Accessory). The ETHICON Bipolar Cable is used to connect the ETHICON Bipolar Scissors to the generator (ESU).

Intended Use

The intended use of the ETHICON Bipolar Scissor is to cut and coagulate soft tissue in open surgical procedures.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

**Indications
Statement**

The ETHICON Bipolar Scissors are non-sterile, reusable devices intended to facilitate cutting and bipolar coagulation of soft tissue in open surgical procedures.

**Technological
Characteristics**

The new device is technologically the same as the predicate except that the device is not designed for endoscopic procedures. This difference does not raise any new questions of safety and effectiveness.

Performance Data

Preclinical laboratory and benchtop evaluations (complies with ANSI/AAMI HF-18) were performed to ensure that the device functions as intended. Clinical data was deemed unnecessary to support the Premarket Notification. Sufficient data has been gathered from pre-clinical and benchtop testing to assess the safety and effectiveness characteristics of the new device.

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.

Contact

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