APR 25 1997 K970317

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.

MODIFIED DEVICE NAME: E-PACK Procedural Kit

PREDICATE DEVICE NAME: Predicate Device E-PACK Procedural Kit

510(k) SUMMARY

Device Description

All components of E-PACK procedural kit are legally marketed devices manufactured by or for ETHICON, Inc. and labeled for approved uses.

These products are packaged together in the form of a "kit" for the convenience of the surgeon.

Intended Use

There is no change in the approved intended use of the device when provided in the procedure kit

Continued on next page

510(k) SUMMARY, Continued

Sterilization

E-Pack procedural kits are sterilized by ethylene oxide for minimum sterility level of 10^{-6}.

Packaging

The component devices in the E-PACK procedure kit may be packaged in their current individual package or paper folders into one large thermoformed blister tray or in a flexible configuration consisting of a sealed pouch.

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

John D. Paulson, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
ETHICON, Inc.
Rt. #22, West
Somerville, NJ 08876-0151

Date

January 24, 1997