K970079

MAR 1 1 1997

Appendices

510(k) Summary of Safety and Effectiveness (App. A)

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) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Device description	The PROXIMATE® Disposable Skin Stapler is a sterile, single patient use instrument designed to deliver rectangular, stainless steel staples for routine wound closure.
Intended use	The New Device is intended for the same use as the Predicate Device. It is intended to be used for routine skin closure.
Indications statement	The indications statement for the New Device and the Predicate Device is the same. The devices are used for routine skin closure in a wide variety of surgical procedures.
Technological characteristics	There are no new technological characteristics in the New Device.
Performance data	A pre-clinical study was conducted to evaluate the cosmetic appearance and perceived ease of extraction of skin staples coated with calcium stearate applied to the PROXIMATE® Disposable Skin Staplers. All results were acceptable.
Conclusion	Based on the 510(k) "Substantial Equivalence" decision-making process 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	Lorri Chavez, Ethicon Endo-Surgery, Inc., 4545 Creek Road, Cincinnati, Ohio 45242
Date	January 8, 1996