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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. **Names of Devices with New Labeling**: • Ethicon Endo-Surgery Endoscopic Articulating Multifeed Stapler with Swiveling Cartridge Tip • Ethicon Endo-Surgery Endoscopic Multifeed Stapler **Predicate Device Names**: • AutoSuture® ENDO Universal 65° Disposable Surgical Stapler
Device description	The Ethicon Endo-Surgery Endoscopic Articulating Multifeed Stapler with Reload Unit is a sterile, single patient-use multi-fire stapler that articulates on a rotating shaft and is intended for use in minimally invasive or open surgical procedures. The device is composed of two primary sections: (1) a reloadable cartridge and (2) a shaft/handle portion. The ETHICON Endoscopic Multifeed Stapler is a sterile, single patient-use multi-fire stapler which provides titanium or stainless steel staples.
Intended use	The New Device is intended for the same use as the Predicate Devices. All of these devices are intended for use in either minimally invasive or open surgical procedures.
Indications statement	The indications statement for the New Device and the Predicate Devices is the same. All of these devices are used for approximating tissue and affixing surgical mesh to tissue.
Technological characteristics	There are no new technological characteristics in the New Device. All of these devices are manually actuated surgical staplers. There are no new materials used in the design of the New Device.

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

Performance data	Pre-clinical and Clinical data were deemed unnecessary for support of this premarket notification.
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	Melissa Walker, Ethicon Endo-Surgery, Inc., 4545 Creek Road, Cincinnati, Ohio 45242.
Date	June 10, 1996