

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

| | |
|--------------------------------------|--|
| 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) 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. |
| Device description | The UltraCision 5mm Hard Sheath LaparoSonic® Blade instruments are 3 styles of sterile, single patient use instruments consisting of a titanium blade with a non-removable sheath. The three styles consist of a Sharp Hook, Dissecting Hook and a Ball Coagulator. The working lengths are approximately 32 cm. The system consists of a blade affixed with a sheath, a hand piece, blade adaptor, blade wrench, generator, foot switch and cart. |
| Intended use | The intended use for the New Device is the same as that of the Predicate Device in that it is for cutting soft tissue and providing hemostasis during endoscopic surgery. |
| Indications statement | The UltraCision 5mm Hard Sheath LaparoSonic® Blade is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels. |
| Technological characteristics | The technological characteristics of the New Devices are the same as the Predicate Device. The same ultrasonic characteristics remain as a method of activation. |
| Performance data | Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance in cutting, blunt tissue dissection and coagulation. |

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

Conclusion

Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Devices are substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

Contact

Lonnie Pace
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Date

June 27, 1996
