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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) 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 ENDOPATH® ETS Endoscopic Linear Cutter and ETS-FLEX Endoscopic Articulating Linear Cutter devices deliver two double-staggered or two triple-staggered rows of staples while simultaneously dividing the tissue between the rows. A "no-knife" version may also be provided. The instrument's safety lock-out feature is designed to prevent a spent reload from being refired. Both the standard and the vascular/thin instruments have a staple line that is 20-60mm long and a cut line of 18-58mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on the ETS-FLEX Endoscopic Articulating Linear Cutter enables bilateral movement of the instrument jaws. The instrument is reloadable with either a standard, blue reload for tissue that is compressible to 1.5mm in thickness, a thick, green reload for tissue that is compressible to 2.0mm in thickness, or a vascular/thin, white reload for tissue that is compressible to 1.0mm in thickness. Do not reload the instrument more than seven times for a maximum of eight firings per instrument.
Intended use	For transection, resection, and/or creation of anatomoses.
Indications statement	The ENDOPATH® ETS Endoscopic Linear Cutter and ETS-FLEX Endoscopic Articulating Linear Cutter have application in general, urologic, gynecologic, and thoracic surgery for transection, resection, and/or creation of anastomoses.

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

Technological characteristics	The technological characteristics of the New Devices are the same as the Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance in transecting, resecting, and/or creation of anastomoses.
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.**
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