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MAY 16 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

The Karl Storz Rigid Telescopes for Obstetrics and Gynecology and their predicate devices are designed to allow viewing of the site during laparoscopic and hysteroscopic surgical procedures. The Karl Storz devices are straight-shafted, rod lens-type rigid telescopes. All body contact materials are commonly used in medical devices for a wide range of applications, and have a long history of biocompatibility for human use.

The Karl Storz Rigid Telescopes for Ob/Gyn are substantially equivalent to the predicate devices, since the basic features, design and intended uses are the same. The minor differences between the Karl Storz Rigid Telescopes for Ob/Gyn and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of the devices.

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