



K955304

510(k) SUMMARY

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Contact/Submitter: Jodi Locher, Manager, Regulatory Affairs
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Trade Name: CRICKET™ Multipurpose Steering Device and Tip Shaper
Common Name: Steering Device and Guide Wire Shaping Device
Classification Name: Steering Device and Wire Shaper

Predicate Devices: ACS Wire Shaper (K862567)
MICROVENA Microtorquer pin vise (K922060)

Device Description: The CRICKET™ is intended to be used as a steering mechanism
Intended Use for guidewires. The opposite end of the CRICKET™ has a shaping bar which allows for shaping the distal tip of guidewires.
(revised February 13, 1996)

Comparative Analysis: The CRICKET™ has the same intended use as the ACS Wire Shaper and the MICROVENA Microtorquer pin vise.

Functional/Safety Testing: All current MICROVENA guidewires were successfully shaped with the CRICKET™ and the guidewires successfully passed visual, functional and tensile strength tests.
(revised February 13, 1996)

Conclusion: The CRICKET™ is substantionally equivalent to the predicate devices based on intended use and the results of functional testing.