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510(k) Summary

SUBMITTER:

Submitted on behalf of:

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DATE SUMMARY PREPARED: 1-22-96

TRADE NAME: SCANLAN® Heifetz Aneurysm Elgiloy® Clip System

COMMON NAME: Aneurysm Clip & Applier System

SUBSTANTIALLY EQUIVALENT TO: Weck Heifetz Aneurysm Clip & Applier System

DESCRIPTION of the DEVICE:

The SCANLAN® Heifetz Aneurysm Elgiloy® Clip System is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent bleeding or bursting.) The SCANLAN® Heifetz Aneurysm Elgiloy® Clip System is sold non-sterile. Descriptions of each clip size and shape are provided in the brochure. Appliers are available in five sizes and are described in the accompanying brochure (See Appendix A.) A schematic for a representative clip size is provided in Appendix B.

INDICATIONS FOR USE:

SCANLAN® Heifetz Aneurysm Elgiloy® Clip System provides standard clips and appliers used to occlude an intracranial aneurysm to prevent it from bleeding or bursting

CLINICAL INFORMATION and SAFETY and EFFECTIVENESS:

SCANLAN® Heifetz Aneurysm Elgiloy® Clip System is substantially equivalent to the Weck Heifetz Aneurysm Clip system (clips and appliers) that are represented in part by K790413. Note that the Weck system (additional clip sizes and shapes) is also a pre-amendment device. There are no substantial differences in materials, designs or performance, in so far as can be determined, between the Weck brand of Heifetz Aneurysm clips and appliers and the Scanlan International products.

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