

K963173

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510(k)

Summary of Safety and Effectiveness

StealthStation™ System Sterilization

- I. Company:** Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709

- II. Product Name:** StealthStation™ System

- III.** This submission describes the addition of the STERRAD®* Sterilization System as a sterilization option for certain components of the StealthStation™ System which was cleared in a previous 510(k) submission. This sterilization option was validated by an independent laboratory in accordance with the AAMI TIR No. 12-1994, *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.*

*STERRAD is a registered trademark of Advanced Sterilization Products, a Division of Johnson and Johnson Medical, Inc.