

K955175

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

- 1. **Trade Name:** ACS ANCHOR™ Exchange Device
- Common Name:** Guide Wire Extension/Exchange Device

- 2. **Device Classification:** Class II

- 3. **Performance Standards:**

Performance standards have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for guide wire extension/exchange devices.

- 4. **Device Description:**

ACS ANCHOR™ Exchange Device

The ACS ANCHOR™ Exchange Device is used within a guiding catheter to facilitate the exchange of an interventional device while maintaining the position of a guide wire within the vasculature. The ACS ANCHOR™ Exchange Device consists of a proximal control handle and a superelastic core wire within a single lumen hypotube approximately 96 cm. long. The control handle provides the user-interface to control the movement of the hypotube and the core wire. During an exchange procedure, the distal end of the core wire is wrapped around the guide wire to lock its position in the vasculature. The ACS ANCHOR™ Exchange Device is compatible with 0.010” through 0.018” diameter non-hydrophilic-coated guide wires and associated interventional devices (except the ROTOBLATOR® Rotational Angioplasty System) when at least 0.015” free space is available within the guiding catheter.

- 5. **Summary of Substantial Equivalence:**

Comparison of the new ANCHOR™ Exchange Device to the predicate device, The Magnet Exchange Device by Scimed Life Systems, Inc. indicates that the ANCHOR™ Exchange Device is substantially equivalent to the predicate exchange device. Like the Magnet Exchange Device, the ACS ANCHOR™ Exchange Device is used to facilitate the exchange of an interventional device without the use of a guide wire extension or exchange length wire. Both the ACS ANCHOR™ Exchange Device and the Magnet Exchange Device are designed to apply a holding force or “lock” on the guide wire to allow withdrawal or advancement of an interventional device over the guide wire while maintaining the guide wire position in the vasculature.

Bench and in vivo testing have been completed to evaluate the performance of the ACS ANCHOR™ Exchange Device in combination with various interventional devices (e.g., PTCA dilatation catheters, atherectomy catheters, stent delivery systems).

6. **Testing Data:**

Biocompatibility

Biocompatibility testing was performed on sterilized ACS ANCHOR™ Exchange Devices according to the International Standard - Biological Evaluation of Medical Devices (ISO 10993-1:1992(E)) and showed that the ACS ANCHOR™ Exchange Device is biocompatible and is acceptable for its intended application.

Bench and In Vivo Testing

Bench testing of the ACS ANCHOR™ Exchange Device consisted of the following tests: tensile tests, torsional strength tests, locking force test, and fatigue (cycling) test. The results of the tests demonstrated that the ACS ANCHOR™ Exchange Device is acceptable for its intended use. Comparison of the holding force between the ACS ANCHOR™ Exchange Device and the predicate device, The Magnet Exchange Device showed that the ACS ANCHOR™ Exchange Device is substantially equivalent to this predicate device.

In vivo testing was conducted to substantiate the use of the ACS ANCHOR™ Exchange Device with different interventional devices.

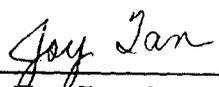
7. **Sterilization:**

The ACS ANCHOR™ Exchange Device is sterilized by the same methods and following the same parameters as those used for currently marketed ACS guide wires and accessories. Sterilization validation of the device was performed and showed that the sterility assurance level (10^{-6}) is achieved.

8. **Conclusion:**

Based on the intended use and results of the testing, the ACS ANCHOR™ Exchange Device is deemed substantially equivalent to the predicate device, The Magnet Exchange Device by Scimed Life Systems, Inc.

Signed:



Joy Yan, Regulatory Affairs Coordinator

000342