



K95 4642
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510(k) SUMMARY

Contact/Submitter: Christine M. Busch, Regulatory Affairs Associate
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Trade Name: The "HyTek" Hydrophilic Guidewire
Common Name: Guidewire
Classification Name: Wire Guide Catheter (per 21 CFR 870.1330)

Predicate Devices: HydroTorque™ Guide Wire (K935232)
ACS HI-TORQUE Guidewires
The "NINER" .009" PTCA Guidewire (K952860)
The M-PATH PTCA Guidewire (K946356)

Device Description: The shaft of the HyTek Guidewire is constructed of Nitinol (nickel titanium alloy). The Nitinol core is a continuous piece of wire extending from the distal tip to the proximal shaft. The distal tip is tapered to provide flexibility and softness. The distal tip is composed of gold plated tungsten wire. The guidewire is coated with a hydrophilic coating to enhance lubricity.

Intended Use: The HyTek Guidewire is intended for general intravascular use to aid in the selective placement of catheters in the coronary and peripheral and visceral vasculature during diagnostic and/or therapeutic procedures.

Functional/Safety

Testing: The HyTek Guidewire successfully underwent all functional and safety testing including tensile strength, torqueability and torque strength, tip flexibility and coating adhesion testing.

Conclusion: The HyTek Guidewire is substantially equivalent to the predicate devices based on the results of the functional testing.

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