

510(k) Summary Of Safety And Effectiveness

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FOI RELEASABLE

Sponsor:	Boston Scientific Corporation One Scientific Place Natick, MA 01760-1537
Contact Person:	Carol J. Holloway Regulatory Affairs Specialist
Submission Date:	December 27, 1996
Description of Device:	The Imager Torque Catheter is a single - lumen introduction catheter with a range of tip configurations. The device is flexible catheter with one hole at the tip. A luer lock hub is attached to the proximal end. The catheter is designed to be used with a .038" guidewire if required.
Intended Uses:	The Imager Torque Catheter is indicated for use for catheterization in the urinary tract or gastrointestinal tract for the introduction of radiopaque contrast materials.
Substantial Equivalence:	The proposed devices are <i>Substantially Equivalent</i> to the predicate currently marketed devices indicated for use for catheterization in the cardiovascular system for the introduction of radiopaque contrast materials and CFR 21 part 878.4200, Introduction / Drainage Catheter.