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510 (k) Summary Of Safety And Effectiveness

K970121

Sponsor: Boston Scientific Corporation
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Description of Device: 2Fr, 8.3 mm Stone Dislodger Basket, Helical Design

Intended Uses: The proposed Stone Dislodger is intended to be used during urological and/or gastroenterological procedures including use during intracorporeal lithotripsy, to endoscopically grasp, manipulate and remove calculi and other foreign objects.

Substantial Equivalence: The proposed devices are "***Substantially Equivalent***" to the predicate devices (K871777, K871779, K925495, K951309) indicated for use during urological and/or gastroenterological procedures to endoscopically grasp, manipulate and remove calculi and other foreign objects.

Product Testing: The proposed devices have been tested and compared to the predicate devices (K871777, K871779, K925495, K951309). The results indicate that the proposed devices are "***Substantially Equivalent***" to the predicate devices in terms of performance characteristics tested.