

K232633 Gold Probe Bipolar Electrohemostasis CatheterNov 28, 2023
90 days to decisionK232633 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Aug 30, 2023
Decision date	Nov 28, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Injection Gold Probe Bipolar Electrohemostasis Catheter

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Lingling Guo
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

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