

**K014297 ENDOVIVE INITIAL PLACEMENT GASTROSTOMY KIT**Jul 9, 2002  
190 days to decisionK014297 · Product code: **KNT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k014297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 31, 2001
Decision date	Jul 9, 2002
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ENDOVIVE LOW PROFILE BUTTON REPLACEMENT GASTROSTOMY TUBE; SECURI-T INITIAL P

**APPLICANT**

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Company	<b>Boston Scientific Corp</b>
Location	San Jose, CA, US
Contact	PAIGE SWEENEY
Website	<a href="https://www.bostonscientific.com/">https://www.bostonscientific.com/</a>
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...