

K161003 EndoVive One Step Button Low Profile Initial Placement PEG Kit with ENFit Connector, EndoVive Low Profile Button Replacement Gastrostomy Tube Kit with ENFit Connector, EndoVive Button Right Angle Feeding Set with ENFit Connector, EndoVive Button Bolus Feeding Set with ENFit Connector, EndoVive Button Decompression Tube with ENFit Connector

Jun 17, 2016
67 days to decision

K161003 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161003/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Apr 11, 2016
Decision date	Jun 17, 2016
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	VIRGINIA GARCIA
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161003/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026