

K150679 EndoVive Initial Placement Standard PEG Kit with ENFit Connector, EndoVive Initial Placement Safety PEG Kit with ENFit Connector

May 29, 2015
73 days to decision

K150679 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150679/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Mar 17, 2015
Decision date	May 29, 2015
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	Virginia Garcia
Website	https://www.bostonscientific.com/
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...