

K891121 MEDI-TECH AMPLATZ INTRODUCER SHEALTH SYSTEM

Dec 5, 1989
278 days to decisionK891121 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k891121/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 2, 1989
Decision date	Dec 5, 1989
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	ALBERT SEPRINSKI
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...