

K896920 SIDEWINDER 40CC DL INTRA-AORTIC BALLOON CATHETER

Mar 6, 1990
84 days to decisionK896920 · Product code: **DSP** · Cardiovascular
Source: <https://www.510kdatabase.net/k896920/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Dec 12, 1989
Decision date	Mar 6, 1990
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	LEO BASTA
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...