FDA 510(k) Premarket Notification

K953023 PRECEDER GUIDEWIRE

CLEARED

Sep 21, 1995
84 days to decision

K953023 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k953023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 29, 1995
Decision date	Sep 21, 1995
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corp**
Location	San Jose, CA, US
Contact	MARY P LEGRAW
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...