

K020028 6F MACH1/34356-XXXJan 22, 2002
18 days to decisionK020028 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k020028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 4, 2002
Decision date	Jan 22, 2002
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary
Other names	5F MACH1/35845-XXX; 7F MACH1/34357-XXX; 8F MACH1/34358-XXX

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	TODD KORNMANN
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...
