FDA 510(k) Premarket Notification

CLEARED

K211080 EkoSonic Endovascular Device

Nov 19, 2021
221 days to decision

K211080 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k211080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Apr 12, 2021
Decision date	Nov 19, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific**
Location	San Jose, CA, US
Contact	Joshua Kim
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. ...