FDA 510(k) Premarket Notification

CLEARED

K213422 EkoSonic Endovascular Device, EKOS+ Endovascular Device

Dec 14, 2021
55 days to decision

K213422 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k213422/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Oct 20, 2021
Decision date	Dec 14, 2021
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Ambreen Athar
Website	https://www.bostonscientific.com
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...