FDA 510(k) Premarket Notification

K213494 Aveir Retrieval Catheter

CLEARED

Apr 1, 2022
151 days to decision

K213494 · Product code: **MMX** · Cardiovascular
Source: https://www.510kdatabase.net/k213494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Percutaneous Retrieval (MMX)
Date received	Nov 1, 2021
Decision date	Apr 1, 2022
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Medical**
Location	S,Mta Clara, CA, US
Contact	Bijal Jain
Website	https://www.abbott.com
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...