FDA 510(k) Premarket Notification

K260304 WAVE PTA Balloon Catheter

CLEARED

May 20, 2026
110 days to decision

K260304 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k260304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jan 30, 2026
Decision date	May 20, 2026
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**WAVE Medical AG**
Location	Neuhausen Am Rheinfall, CH
Contact	Kym Rupp
510(k) history	1 submissions · 1 cleared · 2026-2026