

K260304 WAVE PTA Balloon CatheterMay 20, 2026
110 days to decisionK260304 · 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 Rheinfl, CH |
| Contact | Kym Rupp |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260304/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026