

K152873 Crosstella RX Balloon Dilatation CatheterJan 22, 2016
114 days to decisionK152873 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k152873/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Sep 30, 2015 |
| Decision date | Jan 22, 2016 |
| Days to decision | 114 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | KANEKA Corporation |
| Location | Tokyo, JP |
| Contact | TOSHIHIKO MOTOMINE |
| 510(k) history | 10 submissions · 10 cleared · 2015-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152873/> 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 May 31, 2026