

**K221245 PTA Balloon Dilatation Catheter**Dec 14, 2022  
226 days to decisionK221245 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k221245/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 2, 2022
Decision date	Dec 14, 2022
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Kossel Medtech (Suzhou) Co., Ltd.</b>
Location	Suzhou, CN
Contact	Ron Lv
510(k) history	5 submissions · 5 cleared · 2018-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221245/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026