

**K231402 HP PTA Balloon Dilatation Catheter**Dec 20, 2023  
219 days to decisionK231402 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k231402/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 15, 2023
Decision date	Dec 20, 2023
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231402/> 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