

**K152080 Metacross OTW PTA Balloon Dilatation Catheter**Sep 24, 2015  
59 days to decisionK152080 · Product code: **LIT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152080/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 27, 2015
Decision date	Sep 24, 2015
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KANEKA Corporation</b>
Location	Tokyo, JP
Contact	Toshihiko Motomine
510(k) history	10 submissions · 10 cleared · 2015-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152080/> 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 31, 2026