

**K163479 R2P Metacross RX**Jan 11, 2017  
30 days to decisionK163479 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k163479/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Dec 12, 2016
Decision date	Jan 11, 2017
Days to decision	30 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/k163479/> 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