

**K172264 OTW Takeru PTCA Balloon Dilatation Catheter**Mar 19, 2018  
235 days to decisionK172264 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172264/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jul 27, 2017
Decision date	Mar 19, 2018
Days to decision	235 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/k172264/> 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 30, 2026