

**K173581 Gallant PTCA Dilatation Catheter**Jan 25, 2018  
66 days to decisionK173581 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Nov 20, 2017
Decision date	Jan 25, 2018
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medinol, Ltd.</b>
Location	Tel-Aviv, IL
Contact	Marina Tikhonov Demishtein
510(k) history	6 submissions · 3 cleared · 1998-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173581/> 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