

**K162625 SeQuent Neo Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheters**Jun 12, 2017  
265 days to decisionK162625 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Sep 20, 2016
Decision date	Jun 12, 2017
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B. Braun Interventional Systems, Inc.</b>
Location	Minneapolis, MN, US
Contact	PETER FLOSDORF
510(k) history	3 submissions · 3 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162625/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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