

**K113103 SPLITWIRE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY SCORING DEVICE**May 22, 2012  
216 days to decisionK113103 · Product code: **PNO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Oct 19, 2011
Decision date	May 22, 2012
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rex Medical</b>
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	13 submissions · 11 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113103/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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