

**K092361 REEF HP 0.035 OTW PTA BALLOON DILATATION  
CATHETER**Oct 29, 2009  
86 days to decisionK092361 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k092361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 4, 2009
Decision date	Oct 29, 2009
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Invatec S.P.A.</b>
Location	Bethlehem, PA, US
Contact	JOHN CLAY
510(k) history	4 submissions · 3 cleared · 2009-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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