

**K052791 MODIFICATION TO: AMPHIRION DEEP 0.014 OTW PTA BALLOON CATHETER**

Nov 4, 2005  
32 days to decision

K052791 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k052791/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 3, 2005
Decision date	Nov 4, 2005
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Invatec Innovative Technologies, S.R.L.</b>
Location	Plymouth, MN, US
Contact	STEPHANIE ROBINSON
510(k) history	7 submissions · 7 cleared · 2005-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k052791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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