

**K083919 AMPHIRION DEEP 0.014 OTW PTA BALLOON
CATHETER**Mar 13, 2009
72 days to decisionK083919 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k083919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 31, 2008
Decision date	Mar 13, 2009
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Invatec Innovative Technologies, S.R.L.
Location	Plymouth, MN, US
Contact	STEVE CAMP
510(k) history	7 submissions · 7 cleared · 2005-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083919/>; Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026