

**K092014 SOLOPATH BALLOON EXPANDABLE
TRANSFEMORAL INTRODUCER**Oct 8, 2009
94 days to decisionK092014 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k092014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 6, 2009
Decision date	Oct 8, 2009
Days to decision	94 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	Onset Medical Corporation
Location	Mission Viejo, CA, US
510(k) history	8 submissions · 8 cleared · 2005-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092014/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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