

**K100819 THE SOLOPATH BALLOON EXPANDABLE
TRANSFEMORAL INTRODUCER**Aug 2, 2010
132 days to decisionK100819 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k100819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 23, 2010
Decision date	Aug 2, 2010
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100819/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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