

**K062852 BALLOON EXPANDABLE TRANSSEPTAL
INDRODUCER, MODELS BETI-1840 AND BETI-1870**Feb 23, 2007
151 days to decisionK062852 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k062852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 25, 2006
Decision date	Feb 23, 2007
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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