FDA 510(k) Premarket Notification

# K062852 BALLOON EXPANDABLE TRANSSEPTAL INDRODUCER, MODELS BETI-1840 AND BETI-1870

**CLEARED**

Feb 23, 2007
151 days to decision

K062852 · 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 |