FDA 510(k) Premarket Notification

# K110429 PROSIM 4, PROSIM 6, PROSIM 8

**CLEARED**

Sep 2, 2011
199 days to decision

K110429 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k110429/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT) |
| Date received | Feb 15, 2011 |
| Decision date | Sep 2, 2011 |
| Days to decision | 199 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Fluke Biomedical** |
| Location | Orange, CA, US |
| Contact | JOHN NELSON |
| 510(k) history | 6 submissions · 6 cleared · 2008-2013 |