FDA 510(k) Premarket Notification

K131000 V-PATCH SYSTEM

CLEARED

Jan 8, 2014
273 days to decision

K131000 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k131000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 10, 2013
Decision date	Jan 8, 2014
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intelesens Limited**
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	3 submissions · 3 cleared · 2011-2015