FDA 510(k) Premarket Notification

K150992 Vios Monitoring System

CLEARED

Dec 16, 2015
245 days to decision

K150992 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k150992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Apr 15, 2015
Decision date	Dec 16, 2015
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vios Medical, Inc.**
Location	St. Paul, MN, US
Contact	MEGAN GRAHAM
510(k) history	3 submissions · 3 cleared · 2015-2018