FDA 510(k) Premarket Notification

K160956 LD-Oxi system

CLEARED

Jul 6, 2016
92 days to decision

K160956 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k160956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 5, 2016
Decision date	Jul 6, 2016
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ld Technology, LLC**
Location	Miami, FL, US
Contact	Albert MAAREK
510(k) history	14 submissions · 14 cleared · 2009-2020