FDA 510(k) Premarket Notification

K150691 Datalys Multi-Parameter Patient Monitor

CLEARED

May 15, 2015
58 days to decision

K150691 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k150691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Mar 18, 2015
Decision date	May 15, 2015
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Lutech Industries, Inc.**
Location	Ronkonkoma, NY, US
Contact	RONALD VACHULA
510(k) history	4 submissions · 4 cleared · 2014-2017