

K150691 Datalys Multi-Parameter Patient MonitorMay 15, 2015
58 days to decisionK150691 · 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

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