

**K151512 Star 60**Feb 14, 2016  
255 days to decisionK151512 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k151512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 4, 2015
Decision date	Feb 14, 2016
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skanray Technologies Private Limited</b>
Location	Mysore, IN
Contact	MAHADEVAN J
510(k) history	4 submissions · 4 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151512/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026