

K160899 CoVa Monitoring System 2Jun 22, 2017
447 days to decisionK160899 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k160899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 1, 2016
Decision date	Jun 22, 2017
Days to decision	447 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tosense, Inc.
Location	San Diego, CA, US
Contact	SUSAN PEDE
510(k) history	2 submissions · 2 cleared · 2015-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160899/> Data sourced from FDA 510(k) public records (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. - Generated June 1, 2026