

K111854 AO USB RECEIVER, WI-BOX, WI-BOX PSU KIT, WI-BOX XPRESS CABLE, PW USB RECEIVEROct 21, 2011
114 days to decisionK111854 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k111854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Jun 29, 2011
Decision date	Oct 21, 2011
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. Jude Medical Systems AB
Location	Uppsala, SE
Contact	MIKAEL SJOLANDER
510(k) history	5 submissions · 5 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111854/> 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 5, 2026