

**K042138 FULL AUTO WRIST DIGITAL BLOOD PRESSURE
MONITOR MODEL# SE-311**Aug 24, 2004
15 days to decisionK042138 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k042138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 9, 2004
Decision date	Aug 24, 2004
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sein Electronics Co., Ltd.
Location	Mahwah, NJ, US
Contact	JAY MANSOUR
510(k) history	12 submissions · 12 cleared · 1991-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042138/> 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 28, 2026