

**K141113 SPACELBS MODEL ON TRAK (90227) AMBULATORY
BLOODY PRESSURE (ABP) NON-INVASIVE**Sep 26, 2014
149 days to decisionK141113 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k141113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 30, 2014
Decision date	Sep 26, 2014
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spacelabs Healthcare, Ltd.
Location	Nederland, CO, US
Contact	AL VAN HOUDT
510(k) history	9 submissions · 9 cleared · 2011-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141113/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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