

**K190927 Oscillometric Blood Pressure Monitor**Jun 24, 2019  
76 days to decisionK190927 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190927/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 9, 2019
Decision date	Jun 24, 2019
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rudolf Riester GmbH</b>
Location	Jungingen, DE
Contact	Vivi Ding
510(k) history	3 submissions · 3 cleared · 2017-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190927/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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