FDA 510(k) Premarket Notification

K190927 Oscillometric Blood Pressure Monitor

CLEARED

Jun 24, 2019
76 days to decision

K190927 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k190927/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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