FDA 510(k) Premarket Notification

# K170538 RVS-100 Vital Signs Monitor

**CLEARED**

Oct 17, 2017
236 days to decision

K170538 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k170538/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Feb 23, 2017 |
| Decision date | Oct 17, 2017 |
| Days to decision | 236 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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