

K183534 Fully Automatic Electronic Blood Pressure MonitorMay 16, 2019
148 days to decisionK183534 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k183534/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Dec 19, 2018 |
| Decision date | May 16, 2019 |
| Days to decision | 148 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Andon Health Co, Ltd. |
| Location | Tiajin, CN |
| Contact | Liu Yi |
| 510(k) history | 92 submissions · 92 cleared · 2008-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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