

K083319 FULLY AUTOMATIC ELECTRONIC BLOOD PRESSURE MONITOR, MODEL KD-7941Jan 29, 2009
80 days to decisionK083319 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k083319/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Nov 10, 2008 |
| Decision date | Jan 29, 2009 |
| Days to decision | 80 days |
| Third-party review | 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/k083319/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 23, 2026