

K213503 Wrist Blood Pressure Monitor, models AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D, AOJ-35EFeb 18, 2022
109 days to decisionK213503 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k213503/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received | Nov 1, 2021 |
| Decision date | Feb 18, 2022 |
| Days to decision | 109 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Shenzhen AOJ Medical Technology Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Queena Chen |
| 510(k) history | 17 submissions · 17 cleared · 2018-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213503/> 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 May 25, 2026