

**K254225 Arm Blood Pressure Monitor (HH-802CB, HH-802EB, HH-805CB, HH-812CB, HH-808CL, HH-808EL)**Apr 1, 2026  
93 days to decisionK254225 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k254225/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received         | Dec 29, 2025  |
| Decision date         | Apr 1, 2026   |
| Days to decision      | 93 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shenzhen HanHan Technology Co., Ltd.</b> |
| Location       | Shenzhen, CN                                |
| Contact        | Yong Zhang                                  |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254225/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026