

**K230409 Wrist Type Blood Pressure Monitor (W05,W1101L)**Aug 25, 2023  
191 days to decisionK230409 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230409/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received         | Feb 15, 2023  |
| Decision date         | Aug 25, 2023  |
| Days to decision      | 191 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shenzhen Jamr Technology Co., Ltd.</b> |
| Location       | Shenzhen, CN                              |
| Contact        | Haiyu Zhang                               |
| 510(k) history | 6 submissions · 6 cleared · 2020-2025     |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Shanghai SUNGO Management Consulting Co., Ltd.</b> |
| Contact         | Eva Li  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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