

**K222160 GUS610 Blood pressure monitor**Nov 22, 2022  
125 days to decisionK222160 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k222160/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received         | Jul 20, 2022  |
| Decision date         | Nov 22, 2022  |
| Days to decision      | 125 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Globalcare Medical Technology Co., Ltd.</b> |
| Location       | Zhongshan City, CN                             |
| Contact        | Chiara Cavagnolo                               |
| 510(k) history | 5 submissions · 5 cleared · 2020-2026          |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222160/> 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 14, 2026