

**K112190 PATIENT MONITOR**Nov 9, 2011  
103 days to decisionK112190 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112190/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received         | Jul 29, 2011   |
| Decision date         | Nov 9, 2011  |
| Days to decision      | 103 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Mediana Co., Ltd.</b>                |
| Location       | Flintville, TN, US                      |
| Contact        | CHARLIE MACK                            |
| 510(k) history | 10 submissions · 10 cleared · 2005-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112190/> 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 June 18, 2026