

**K250226 Clarius Median Nerve AI**May 8, 2025  
101 days to decisionK250226 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k250226/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received         | Jan 27, 2025   |
| Decision date         | May 8, 2025  |
| Days to decision      | 101 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | Yes - Predetermined Change Control Plan (AI/SaMD)      |
| Summary / Statement   | Summary  |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Clarius Mobile Health Corp.</b>      |
| Location       | Vancouver, CA                           |
| Contact        | Agatha Szeliga                          |
| 510(k) history | 12 submissions · 12 cleared · 2016-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250226/> 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