

**K190536 Mediracer NCS**Sep 25, 2019  
205 days to decisionK190536 · Product code: **JXE** · Neurology  
Source: <https://www.510kdatabase.net/k190536/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Nerve Conduction Velocity Measurement (JXE)
Date received	Mar 4, 2019
Decision date	Sep 25, 2019
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mediracer OY</b>
Location	Oulu, FI
Contact	Lassi Laitinen
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190536/> 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 28, 2026