

**K202861 Needle Stimulator**Aug 27, 2021  
333 days to decisionK202861 · Product code: **BWK** · Neurology  
Source: <https://www.510kdatabase.net/k202861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electro-acupuncture (BWK)
Date received	Sep 28, 2020
Decision date	Aug 27, 2021
Days to decision	333 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wuxi Jiajian Medical Instrument Co., Ltd.</b>
Location	Wuxi, CN
Contact	Caihong Sun
510(k) history	12 submissions · 12 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202861/> 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 25, 2026