

**K232121 Power wheelchair (Model:BC-EA8000)**Sep 15, 2023  
60 days to decision

K232121 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k232121/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Jul 17, 2023
Decision date	Sep 15, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ningbo Baichen Medical Devices Co., Ltd.</b>
Location	Ningbo, CN
Contact	Wu Xiao Long
510(k) history	3 submissions · 3 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Jarvis Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232121/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026