

**K250475 Electric Wheelchair (BC-EA5516, BC-EC8002, BC-EC8003, BC-EALD3)**May 27, 2025  
97 days to decisionK250475 · Product code: ITI · Physical Medicine  
Source: <https://www.510kdatabase.net/k250475/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wheelchair, Powered (ITI)          |
| Date received         | Feb 19, 2025                       |
| Decision date         | May 27, 2025                       |
| Days to decision      | 97 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

|                 |   |
|-----------------|---|
| Consulting firm | <b>Shanghai SUNGO Management Consulting Co., Ltd.</b> |
| Contact         | Luna Hu   |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250475/>; Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026