

K201461 Manual Wheelchair, Model A011May 21, 2021
353 days to decisionK201461 · Product code: **IOR** · Physical Medicine
Source: <https://www.510kdatabase.net/k201461/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wheelchair, Mechanical (IOR) |
| Date received | Jun 2, 2020 |
| Decision date | May 21, 2021 |
| Days to decision | 353 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Ningbo Shenyu Medical Equipment Co.,Ltd |
| Location | Yuyao, CN |
| Contact | Zhou Yuefeng |
| 510(k) history | 4 submissions · 4 cleared · 2021-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai SUNGO Management Consulting Co., Ltd. |
| Contact | Vivi Shi |

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.netDevice record: <https://www.510kdatabase.net/k201461/> 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 25, 2026