

**K252687 Manual Wheelchair (HM305-Air1, HM305-Air2)**Nov 21, 2025  
87 days to decisionK252687 · Product code: **IOR** · Physical MedicineSource: <https://www.510kdatabase.net/k252687/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Mechanical (IOR)
Date received	Aug 26, 2025
Decision date	Nov 21, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Suzhou Master Machinery Manufacturing Co.,Ltd</b>
Location	Kunshan, CN
Contact	Wu Hongying
510(k) history	6 submissions · 6 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Xiang Shouqiu

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/k252687/> 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 13, 2026