

K103212 ROUGHRIDERJan 3, 2011
63 days to decisionK103212 · Product code: **IOR** · Physical Medicine
Source: <https://www.510kdatabase.net/k103212/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wheelchair, Mechanical (IOR) |
| Date received | Nov 1, 2010 |
| Decision date | Jan 3, 2011 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Whirlwind Wheelchair International |
| Location | San Francisco, CA, US |
| Contact | MARC KRIZACK |
| 510(k) history | 1 submissions · 1 cleared · 2011-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103212/> 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 June 20, 2026