

**K120976 MANUKA IG**May 23, 2012  
51 days to decisionK120976 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k120976/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Dressing, Wound, Drug (FRO)        |
| Date received         | Apr 2, 2012                        |
| Decision date         | May 23, 2012                       |
| Days to decision      | 51 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Links Medical Products, Inc.</b>   |
| Location       | Laguna Niguel, CA, US                 |
| Contact        | James Smith                           |
| 510(k) history | 4 submissions · 4 cleared · 2012-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120976/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 7, 2026