

**K010623 RECONSTITUTION KIT & VIAL CONNECTOR**Apr 5, 2001  
34 days to decisionK010623 · Product code: **LHI** · General Hospital  
Source: <https://www.510kdatabase.net/k010623/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Set, I.v. Fluid Transfer (LHI)     |
| Date received         | Mar 2, 2001                        |
| Decision date         | Apr 5, 2001                        |
| Days to decision      | 34 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Bioject, Inc.</b>                  |
| Location       | Portland, OR, US                      |
| Contact        | NANCY GERTLAR                         |
| 510(k) history | 9 submissions · 9 cleared · 1987-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010623/> 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 23, 2026