

**K950131 1.0MM 1.8MMO.D. POLYURETHANE DETACHED  
MODEL**Mar 23, 1995  
69 days to decisionK950131 · Product code: **LJT** · General Hospital  
Source: <https://www.510kdatabase.net/k950131/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT) |
| Date received         | Jan 13, 1995  |
| Decision date         | Mar 23, 1995  |
| Days to decision      | 69 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Therex Corp.</b>                     |
| Location       | Walpole, MA, US                         |
| Contact        | BRADLEY J ENEGREN                       |
| 510(k) history | 26 submissions · 23 cleared · 1988-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950131/> 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 July 6, 2026