

**K113214 TLINK DATA MANAGEMENT SYSTEM (DMS)**Feb 7, 2012  
99 days to decisionK113214 · Product code: **DXJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113214/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Display, Cathode-ray Tube, Medical (DXJ) |
| Date received         | Oct 31, 2011                             |
| Decision date         | Feb 7, 2012                              |
| Days to decision      | 99 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Terumo Cardiovascular Systems Corp.</b> |
| Location       | Elkton, MD, US                             |
| Contact        | REBECCA ANDERSEN                           |
| 510(k) history | 43 submissions · 43 cleared · 2000-2015    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113214/> 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 May 25, 2026