

**K071263 NXSTAGE TRAVEL WARMER, MODELS TW-400 & FWS-500**Aug 24, 2007  
109 days to decisionK071263 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k071263/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI) |
| Date received         | May 7, 2007   |
| Decision date         | Aug 24, 2007  |
| Days to decision      | 109 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nxstage Medical, Inc.</b>            |
| Location       | Tewksburt, MA, US                       |
| Contact        | NORMA LEMAY                             |
| 510(k) history | 51 submissions · 51 cleared · 2001-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071263/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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