

K131739 NXSTAGE CONNECTED HEALTH SYSTEMOct 10, 2013
119 days to decisionK131739 · Product code: **FKP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131739/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Dialysate Delivery, Single Patient (FKP) |
| Date received | Jun 13, 2013 |
| Decision date | Oct 10, 2013 |
| Days to decision | 119 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nxstage Medical, Inc. |
| Location | Tewksburt, MA, US |
| Contact | MARY LOU STROUMBOS |
| 510(k) history | 51 submissions · 51 cleared · 2001-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131739/> Data sourced from FDA 510(k) public records (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. - Generated June 1, 2026