

**K081043 LEAK DETECTION SENSOR AND TRAY ACCESSORY
KIT**Jul 7, 2008
84 days to decisionK081043 · Product code: **KOC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k081043/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessories, Blood Circuit, Hemodialysis (KOC) |
| Date received | Apr 14, 2008 |
| Decision date | Jul 7, 2008 |
| Days to decision | 84 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/k081043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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