

K123320 DIMENSION AMMONIA FLEX REAGENT CARTRIDGEFeb 15, 2013
112 days to decisionK123320 · Product code: **JIF** · Chemistry
Source: <https://www.510kdatabase.net/k123320/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzymatic Method, Ammonia (JIF) |
| Date received | Oct 26, 2012 |
| Decision date | Feb 15, 2013 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Healthcare Diagnostics |
| Location | Newark, DE, US |
| Contact | ROSE T MARINELLI |
| 510(k) history | 92 submissions · 92 cleared · 2008-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123320/> 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 May 28, 2026