

K001569 INFINITY AMYLASE REAGENT (PROCEDURE NO. 580/568)Jun 26, 2000
38 days to decisionK001569 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k001569/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catalytic Methods, Amylase (JFJ) |
| Date received | May 19, 2000 |
| Decision date | Jun 26, 2000 |
| Days to decision | 38 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sigma Diagnostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | WILLIAM R GILBERT |
| 510(k) history | 164 submissions · 164 cleared · 1984-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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