

K860530 AMYLASE REAGENT SET (MODIFIED CARAWAY)Feb 28, 1986
16 days to decisionK860530 · Product code: **CJA** · Chemistry
Source: <https://www.510kdatabase.net/k860530/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Amyloclastic, Amylase (CJA) |
| Date received | Feb 12, 1986 |
| Decision date | Feb 28, 1986 |
| Days to decision | 16 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Sterling Diagnostics, Inc. |
| Location | Sterling Heights, MI, US |
| Contact | DAVID L CALLENDER |
| 510(k) history | 41 submissions · 41 cleared · 1985-1993 |

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