

K803060 FOLATE 125I RADIOIMMUNOASSAYDec 22, 1980
101 days to decisionK803060 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k803060/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Acid, Folic, Radioimmunoassay (CGN) |
| Date received | Sep 12, 1980 |
| Decision date | Dec 22, 1980 |
| Days to decision | 101 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Corning Medical & Scientific |
| Location | Mchenry, IL, US |
| Website | https://www.corning.com |
| 510(k) history | 111 submissions · 111 cleared · 1976-1988 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k803060/>, 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 14, 2026