

K802316 PDS THERMAL DILUTION CARDIAC MODULE(OUT)Nov 26, 1980
64 days to decisionK802316 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k802316/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Pre-programmed, Single-function (DXG) |
| Date received | Sep 23, 1980 |
| Decision date | Nov 26, 1980 |
| Days to decision | 64 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | General Electric Co. |
| Location | Mchenry, IL, US |
| 510(k) history | 254 submissions · 254 cleared · 1976-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k802316/> 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 17, 2026