

K831185 CARDIAC OUTPUT MEASURE SYSTEMMay 27, 1983
45 days to decisionK831185 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k831185/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Flow Directed (DYG) |
| Date received | Apr 12, 1983 |
| Decision date | May 27, 1983 |
| Days to decision | 45 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Cook, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 190 submissions · 179 cleared · 1976-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k831185/> 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