

K842503 GAMBRO PULSATILE MONITOR PLM 10-200Aug 10, 1984
45 days to decisionK842503 · Product code: **DWA** · CardiovascularSource: <https://www.510kdatabase.net/k842503/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Control, Pump Speed, Cardiopulmonary Bypass (DWA) |
| Date received | Jun 26, 1984 |
| Decision date | Aug 10, 1984 |
| Days to decision | 45 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Gambro, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 86 submissions · 86 cleared · 1976-2009 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k842503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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