

K961845 PERCUPUMP II WITH EDAJan 23, 1997
255 days to decisionK961845 · Product code: **DSB** · Radiology
Source: <https://www.510kdatabase.net/k961845/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plethysmograph, Impedance (DSB) |
| Date received | May 13, 1996 |
| Decision date | Jan 23, 1997 |
| Days to decision | 255 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | E-Z-Em, Inc. |
| Location | Mchenry, IL, US |
| Contact | PETER APRILE |
| 510(k) history | 56 submissions · 56 cleared · 1977-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961845/> 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 18, 2026