

K914382 LIFE-AIR 1000 HYPOTHERMIC TREATMENT SYSTEMApr 21, 1992
203 days to decisionK914382 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k914382/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Thermal Regulating (DWJ) |
| Date received | Oct 1, 1991 |
| Decision date | Apr 21, 1992 |
| Days to decision | 203 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Progressive Dynamics, Inc. |
| Location | Marshall, MI, US |
| Contact | DAVID DYKEHOUSE |
| 510(k) history | 7 submissions · 7 cleared · 1992-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914382/> 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 July 1, 2026