

K910107 DURAFLO II HEPARIN OXYGENATOR MODEL UNIVOX GOLDApr 10, 1991
90 days to decisionK910107 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k910107/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Jan 10, 1991 |
| Decision date | Apr 10, 1991 |
| Days to decision | 90 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Healthcare Corp |
| Location | Mchenry, IL, US |
| Contact | DONALD A RAIBLE |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910107/>; 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