

K962981 CAPIOX SP PUMP HEADFeb 25, 1997
208 days to decisionK962981 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k962981/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM) |
| Date received | Aug 1, 1996 |
| Decision date | Feb 25, 1997 |
| Days to decision | 208 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Medical Corp. |
| Location | Elkton, MD, US |
| Contact | SANDI HARTKA |
| 510(k) history | 143 submissions · 143 cleared · 1980-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962981/> 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 27, 2026