

**K961000 CAPIOX SX18 HOLLOW FIBER OXYGENATOR WITH  
AND WITHOUT DETACHABLE HARDSHELL RESERVOIR**Oct 2, 1996  
204 days to decisionK961000 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k961000/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 12, 1996
Decision date	Oct 2, 1996
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961000/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026