

**K970463 CAPIOX E HOLLOW FIBER OXYGENATOR WITH
INTEGRATED HEAT EXCHANGER/ARTERIAL RESERVOIR**May 6, 1997
89 days to decisionK970463 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k970463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 6, 1997
Decision date	May 6, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

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/k970463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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