

K883054 SCIMED ULTROX TRUE MEMBRANE OXY. ULTROX I & IISep 26, 1988
69 days to decisionK883054 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k883054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 19, 1988
Decision date	Sep 26, 1988
Days to decision	69 days
Third-party review	No

APPLICANT

Company	Scimed Life Systems, Inc.
Location	Mchenry, IL, US
Contact	SWANSON LANO
510(k) history	109 submissions · 108 cleared · 1977-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883054/>; 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 June 29, 2026