

**K894103 SCIMED ULTROX TRUE MEMBRANE OXYGEN SYST,  
ULTROX II**Sep 21, 1989  
104 days to decisionK894103 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k894103/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 9, 1989
Decision date	Sep 21, 1989
Days to decision	104 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894103/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026