

**K901249 PLEXUS 3.5(TM) PEDIATRIC HOLLOW FIBER  
OXYGENATOR**Jun 11, 1990  
87 days to decisionK901249 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k901249/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 16, 1990
Decision date	Jun 11, 1990
Days to decision	87 days
Third-party review	No

**APPLICANT**

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Company	<b>Shiley, Inc.</b>
Location	Mchenry, IL, US
Contact	ABATI, PHD
510(k) history	174 submissions · 174 cleared · 1976-1993

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901249/>; 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 May 26, 2026