

K831894 BLOOD OXYGENATOR 5070Oct 20, 1983
128 days to decisionK831894 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k831894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 14, 1983
Decision date	Oct 20, 1983
Days to decision	128 days
Third-party review	No

APPLICANT

Company	Shiley, Inc.
Location	Mchenry, IL, US
510(k) history	174 submissions · 174 cleared · 1976-1993

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Device record: <https://www.510kdatabase.net/k831894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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