

K810470 SHILEY S-100A (ADULT) BLOOD OXYGENATORApr 17, 1981
53 days to decisionK810470 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k810470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 23, 1981
Decision date	Apr 17, 1981
Days to decision	53 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/k810470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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