

K811204 BRONCHEK-SHILEY CARDIAC JACKET & BSC JMay 21, 1981
20 days to decisionK811204 · Product code: **DTR** · CardiovascularSource: <https://www.510kdatabase.net/k811204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	May 1, 1981
Decision date	May 21, 1981
Days to decision	20 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/k811204/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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