

K800549 MODEL TRIEX-L HOLLOW FIBER DIALYZERApr 10, 1980
31 days to decisionK800549 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k800549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Mar 10, 1980
Decision date	Apr 10, 1980
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Extracorporeal Medical Specialities, Inc.
Location	Mchenry, IL, US
510(k) history	69 submissions · 69 cleared · 1976-1984

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Device record: <https://www.510kdatabase.net/k800549/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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