

K801194 CLIRANS TE07 HOLLOW FIBER DIALYZERAug 12, 1980
85 days to decisionK801194 · Product code: **FJI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	May 19, 1980
Decision date	Aug 12, 1980
Days to decision	85 days
Third-party review	No

APPLICANT

Company	Terumo America, Inc.
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1981

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Device record: <https://www.510kdatabase.net/k801194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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