

**K011537 DYNAMIC HOLLOW FIBER DIALYZER DS-SERIES,
MODEL: POLYSULFONE 100 HFS, POLYSULFONE 130 HFS**

Jan 7, 2002
234 days to decision

K011537 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011537/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 18, 2001
Decision date	Jan 7, 2002
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dynamic Technology Corp.
Location	Hsinchu, TW
Contact	YAW C YANG
510(k) history	4 submissions · 4 cleared · 1997-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k011537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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