FDA 510(k) Premarket Notification

K812890 HEMASITE GRAFTLESS VASCULAR ACESS

CLEARED

Nov 16, 1981
32 days to decision

K812890 · Product code: **FIQ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k812890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, A-v Shunt (FIQ)
Date received	Oct 15, 1981
Decision date	Nov 16, 1981
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Renal Systems, Inc.**
Location	Mchenry, IL, US
510(k) history	35 submissions · 35 cleared · 1977-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k812890/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026