

K772423 SPIRAFLOW DIALYZERSJan 26, 1978
29 days to decisionK772423 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k772423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Dec 28, 1977
Decision date	Jan 26, 1978
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Bentley Laboratories, Inc.
Location	Mchenry, IL, US
Website	https://www.bentleyinstruments.com
510(k) history	55 submissions · 55 cleared · 1976-1993

Bentley Laboratories, Inc. is located in McHenry, US. The company has a historical record of FDA 510(k) device clearances spanning from 1976 to 1993. Bentley Laboratories received FDA 510(k) clearances from total submissions. The company specialized primarily in Cardiovascular devices, which represented approximately 80% of its regulatory submissions. Notable cleared devices included blood cardioplegia heat exchangers, venous reservoir bags, membrane oxygenators, and central venous catheters used in cardiac surgery and perfusion applications. The company is inactive and s...

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