FDA 510(k) Premarket Notification

K903641 QUICK PRIME HEMOCONCEN. NO. HQ-7000 AND CBP-7000Q

CLEARED

Nov 9, 1990
87 days to decision

K903641 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k903641/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 14, 1990
Decision date	Nov 9, 1990
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Bentley Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	DONALD RAILBE
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...