FDA 510(k) Premarket Notification

K820679 PEDIATRIC ARTERIAL BLOOD FILTER #AF-540

CLEARED

Jun 17, 1982
98 days to decision

K820679 · Product code: **DTM** · Cardiovascular
Source: https://www.510kdatabase.net/k820679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Mar 11, 1982
Decision date	Jun 17, 1982
Days to decision	98 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...