

K931967 HE-30 GOLDJul 13, 1993
83 days to decisionK931967 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k931967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Apr 21, 1993
Decision date	Jul 13, 1993
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bentley Laboratories, Inc.
Location	Mchenry, IL, US
Contact	PAUL J ZALESKY
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...
