FDA 510(k) Premarket Notification

CLEARED

K901250 PLEXUS 2(TM) INFANT HOLLOW FIBER OXYGENATOR

Jun 11, 1990
87 days to decision

K901250 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k901250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 16, 1990
Decision date	Jun 11, 1990
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Shiley, Inc.**
Location	Mchenry, IL, US
Contact	ABATI, PHD
510(k) history	174 submissions · 174 cleared · 1976-1993