FDA 510(k) Premarket Notification

K931444 PLEXUS 2 & 3.5 HOLLOW FIBER OXYGENATORS

CLEARED

May 27, 1994
431 days to decision

K931444 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k931444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 22, 1993
Decision date	May 27, 1994
Days to decision	431 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sorin Biomedica, Fiat, USA, Inc.**
Location	Mchenry, IL, US
Contact	DAVID TAYLOR
510(k) history	20 submissions · 20 cleared · 1980-1994