FDA 510(k) Premarket Notification

K001795 THE AVITRO LLC, 10 AND 100 USO UNITS/ML HEPARIN SODIUM VAFD

CLEARED

Oct 19, 2000
127 days to decision

K001795 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k001795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jun 14, 2000
Decision date	Oct 19, 2000
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avitro, LLC**
Location	Woodstock, IL, US
Contact	JOHN BRDA
510(k) history	2 submissions · 2 cleared · 2000-2000