FDA 510(k) Premarket Notification

K080472 SEDAT MYSHELL LITE

CLEARED

Apr 23, 2008
62 days to decision

K080472 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k080472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Feb 21, 2008
Decision date	Apr 23, 2008
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sedat**
Location	San Diego, CA, US
Contact	LAETITIA COUSIN
510(k) history	3 submissions · 3 cleared · 2006-2008