FDA 510(k) Premarket Notification

CLEARED

K061832 JOSTRA HLM TUBING SETS WITH SAFELINE COATING

Aug 11, 2006
43 days to decision

K061832 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k061832/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jun 29, 2006
Decision date	Aug 11, 2006
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiopulmonary, AG**
Location	Fairfield, IA, US
Contact	JAMES COLLIE
510(k) history	44 submissions · 44 cleared · 2005-2015