FDA 510(k) Premarket Notification

K130639 ELITE-I (BI) DUAL LUMEN CATHETER

CLEARED

May 16, 2013
66 days to decision

K130639 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k130639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 11, 2013
Decision date	May 16, 2013
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary
Other names	ELITE-I (RA) DUAL LUMEN CATHETER; ELITE-I (BIX)DUAL LUMEN CATHETER

APPLICANT

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