FDA 510(k) Premarket Notification

K053025 JOSTRA HLM TUBING SET

CLEARED

Nov 10, 2005
14 days to decision

K053025 · Product code: **DWE** · Cardiovascular
Source: https://www.510kdatabase.net/k053025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Oct 27, 2005
Decision date	Nov 10, 2005
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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