FDA 510(k) Premarket Notification

K121139 ACCUMESH DEPLOYMENT SYSTEM

CLEARED

May 2, 2012
16 days to decision

K121139 · Product code: **ORQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k121139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Deployer (ORQ)
Date received	Apr 16, 2012
Decision date	May 2, 2012
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	JAMES MCMAHON
510(k) history	89 submissions · 86 cleared · 2010-2026