FDA 510(k) Premarket Notification

K121170 RESIN 11

CLEARED

Jul 13, 2012
87 days to decision

K121170 · Product code: **BYI** · Anesthesiology
Source: https://www.510kdatabase.net/k121170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	Apr 17, 2012
Decision date	Jul 13, 2012
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Respinnovation Sas**
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	1 submissions · 1 cleared · 2012-2012