FDA 510(k) Premarket Notification

K062401 MODIFICATION TO LUCAS

CLEARED

Sep 28, 2006
43 days to decision

K062401 · Product code: **DRM** · Cardiovascular
Source: https://www.510kdatabase.net/k062401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Cardiac, External (DRM)
Date received	Aug 16, 2006
Decision date	Sep 28, 2006
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jolife AB**
Location	Washington, DC, US
Contact	HOWARD M HOLSTEIN
510(k) history	5 submissions · 5 cleared · 2006-2018