FDA 510(k) Premarket Notification

CLEARED

K070034 REPROCESSED GUIDANT CARDIAC STABILIZATION AND POSITIONING DEVICES

Aug 17, 2007
226 days to decision

K070034 · Product code: **NQG** · Cardiovascular
Source: https://www.510kdatabase.net/k070034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stabilizer, Heart, Non-compression, Reprocessed (NQG)
Date received	Jan 3, 2007
Decision date	Aug 17, 2007
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ascent Healthcare Solutions**
Location	Phoenix, AZ, US
Contact	KATIE BRAY
510(k) history	21 submissions · 21 cleared · 2006-2011