FDA 510(k) Premarket Notification

K061759 REPROCESSED EXTERNAL FIXATION DEVICE

CLEARED

Sep 5, 2006
75 days to decision

K061759 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k061759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jun 22, 2006
Decision date	Sep 5, 2006
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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