FDA 510(k) Premarket Notification

K052137 ASCENSION MUH

CLEARED

Nov 3, 2005
90 days to decision

K052137 · Product code: **KXE** · Orthopedic
Source: https://www.510kdatabase.net/k052137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Hemi-, Ulnar (KXE)
Date received	Aug 5, 2005
Decision date	Nov 3, 2005
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ascension Orthopedics, Inc.**
Location	Austin, TX, US
Contact	GLEN NEALLY
510(k) history	22 submissions · 22 cleared · 2002-2024