FDA 510(k) Premarket Notification

K072568 MODIFICATION TO OASYS SYSTEM

CLEARED

Oct 5, 2007
23 days to decision

K072568 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k072568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Sep 12, 2007
Decision date	Oct 5, 2007
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Spine**
Location	Allendale, NJ, US
Contact	SIMONA VOIC
510(k) history	74 submissions · 73 cleared · 2004-2026