FDA 510(k) Premarket Notification

K100865 AVA NAVIGATOR PEEK SPACERS, MODEL 48392XXX, 48393XXX

CLEARED

Aug 11, 2010
135 days to decision

K100865 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k100865/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 29, 2010
Decision date	Aug 11, 2010
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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