FDA 510(k) Premarket Notification

K090408 MODIFICATION TO: DSS STABILIZATION SYSTEM

CLEARED

Mar 20, 2009
30 days to decision

K090408 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k090408/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 18, 2009
Decision date	Mar 20, 2009
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Paradigm Spine, LLC**
Location	Washington, DC, US
Contact	ADAM HERDER
510(k) history	11 submissions · 4 cleared · 2008-2016