FDA 510(k) Premarket Notification

K080143 MODIFICATION TO STRYKER SPINE OASYS SYSTEM

CLEARED

Feb 14, 2008
23 days to decision

K080143 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k080143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jan 22, 2008
Decision date	Feb 14, 2008
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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