FDA 510(k) Premarket Notification

K083230 MERCURY SPINAL SYSTEM

CLEARED

Dec 3, 2008
30 days to decision

K083230 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k083230/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 3, 2008
Decision date	Dec 3, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Elements, Inc.**
Location	Carlsbad, CA, US
Contact	KERRI DIMARTINO
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083230/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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