FDA 510(k) Premarket Notification

K133455 CROSSFUSE II CORONAL TAPER, CROSSFUSE II HYPERLORDOTIC

CLEARED

Mar 27, 2014
135 days to decision

K133455 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k133455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 12, 2013
Decision date	Mar 27, 2014
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pioneer Surgical Technology, Inc.**
Location	Marquette, MI, US
Contact	EMILY DOWNS
510(k) history	26 submissions · 26 cleared · 2010-2025