

K140787 PLS (POSTERIOR LUMBAR SYSTEM)May 30, 2014
60 days to decisionK140787 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k140787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 31, 2014
Decision date	May 30, 2014
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sintea Plustek, LLC
Location	Miami Beach, FL, US
Contact	RICH JANSEN
510(k) history	3 submissions · 3 cleared · 2012-2014

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