

**K112611 SINTEA PLUSTEK PLS MULTI-AXIAL SCREWS**Apr 25, 2012  
231 days to decisionK112611 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k112611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 7, 2011
Decision date	Apr 25, 2012
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sintea Plastek, LLC</b>
Location	Miami Beach, FL, US
Contact	DANIELLE WERNIKOWSKI
510(k) history	2 submissions · 2 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112611/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 18, 2026