

**K112861 SINTEA PLUSTEK ANTERIOR CERVICAL PLATE SYSTEM**

Feb 24, 2012  
147 days to decision

K112861 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k112861/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 30, 2011
Decision date	Feb 24, 2012
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sintea Plustek, LLC</b>
Location	Miami Beach, FL, US
Contact	DANIELLE WERNIKOWSKI
510(k) history	3 submissions · 3 cleared · 2012-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k112861/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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