

**K182489 4CIS® Pinehurst Anterior Cervical Plate system**Jan 16, 2019  
127 days to decisionK182489 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k182489/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 11, 2018
Decision date	Jan 16, 2019
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Solco Biomedical Co., Ltd.</b>
Location	Bethesda, MD, US
Contact	Il Kim
510(k) history	17 submissions · 17 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182489/> 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 26, 2026