

**K162685 2-Piece Hammertoe Correction System**Jun 9, 2017  
256 days to decisionK162685 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k162685/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 26, 2016
Decision date	Jun 9, 2017
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Life Spine, Inc.</b>
Location	Hoffman Estates, IL, US
Contact	Randy Lewis
Website	<a href="http://www.lifespine.com/">http://www.lifespine.com/</a>
510(k) history	82 submissions · 82 cleared · 2011-2026

Life Spine, Inc. is a spinal medical device company headquartered in Huntley, Illinois. Founded in 2004, the company develops innovative solutions for spinal pathology across the cervical, thoracic, and lumbar spine. Life Spine serves 32 countries and employs over 70 people worldwide. The company has received FDA 510(k) clearances from total submissions since 2011. Life Spine specializes exclusively in Orthopedic devices, with a focus on minimally invasive spinal fusion solutions. The latest clearance was in 2026, confirming active regulatory engagement. Life Spine's prod...

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