

K161037 Tarsa-Link Stand-Alone Wedge Fixation SystemAug 15, 2016
124 days to decisionK161037 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k161037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 13, 2016
Decision date	Aug 15, 2016
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Life Spine, Inc.
Location	Hoffman Estates, IL, US
Contact	RANDY LEWIS
Website	http://www.lifespine.com/
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...
