

K001535 ZENITH PLATE SYSTEM, ANTERIOR SPINAL INSTRUMENTATION

Mar 20, 2001
307 days to decision

K001535 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k001535/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	May 17, 2000
Decision date	Mar 20, 2001
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Tec, LLC
Location	Pleasant Hill, CA, US
Contact	DAVID W SCHLERF
510(k) history	22 submissions · 22 cleared · 1999-2004

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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