

**K043355 SINTEA BIOTECH POSTERIOR LUMBAR SYSTEM
WITH POLYAXIAL AND RECOVERY SCREWS, MODEL
PLS.01.T5.X**Dec 17, 2004
11 days to decisionK043355 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k043355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Dec 6, 2004
Decision date	Dec 17, 2004
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sintea Biotech, Inc.
Location	Miami Beach, FL, US
Contact	GUIDO ZORZOLI
510(k) history	10 submissions · 10 cleared · 2002-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043355/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026