

K081631 SINTEA BIOTECH PLS MULTI-AXIAL SCREWSJul 18, 2008
37 days to decisionK081631 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k081631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jun 11, 2008
Decision date	Jul 18, 2008
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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