

**K031154 SINTEA BIOTECH SCHANZ SCREW, MODEL  
TFX.SS.XX.X**Jun 24, 2003  
74 days to decisionK031154 · Product code: **JDW** · Orthopedic  
Source: <https://www.510kdatabase.net/k031154/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Threaded (JDW)
Date received	Apr 11, 2003
Decision date	Jun 24, 2003
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sintea Biotech, Inc.</b>
Location	Miami Beach, FL, US
Contact	MARIANNE GRUNWALDT
510(k) history	10 submissions · 10 cleared · 2002-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031154/> 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