

K082679 LAKI HAND FIXATION SYSTEM, MODEL TFX.3X.06.XApr 7, 2009
204 days to decisionK082679 · Product code: **JEC** · Orthopedic
Source: <https://www.510kdatabase.net/k082679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Component, Traction, Invasive (JEC)
Date received	Sep 15, 2008
Decision date	Apr 7, 2009
Days to decision	204 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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