FDA 510(k) Premarket Notification

K022065 SINTEA BIOTECH TRAUMAFIX SYSTEM, MODEL TFX.00.00.X

CLEARED

Aug 6, 2002
42 days to decision

K022065 · Product code: **JEC** · Orthopedic
Source: https://www.510kdatabase.net/k022065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Jun 25, 2002
Decision date	Aug 6, 2002
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k022065/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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