

**K112218 ACE-FISCHER(R), TEMPFIX(R), HOFFMAN
CLASSIC(TM) EXTERNAL FIXATORS**Dec 15, 2011
135 days to decisionK112218 · Product code: KTT · Orthopedic
Source: <https://www.510kdatabase.net/k112218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Aug 2, 2011
Decision date	Dec 15, 2011
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Orthopaedics, Inc.
Location	Warsaw, IN, US
Contact	SUZANA OTANO
510(k) history	206 submissions · 204 cleared · 1998-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112218/>; 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 26, 2026