

K081284 VARIAX DISTAL FIBULA PLATEJul 18, 2008
73 days to decisionK081284 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k081284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	May 6, 2008
Decision date	Jul 18, 2008
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp.
Location	Allendale, NJ, US
Contact	ANDREA M DWYER
510(k) history	288 submissions · 288 cleared · 1999-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081284/> 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 15, 2026