

K080805 MODIFICATION TO VERTEX RECONSTRUCTION SYSTEMApr 18, 2008
28 days to decisionK080805 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k080805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Mar 21, 2008
Decision date	Apr 18, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek
Location	Memphis, TN, US
Contact	CHRISTINE SCIFERT
510(k) history	154 submissions · 147 cleared · 2002-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080805/> 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 16, 2026