

K980852 GII SPINAL FIXATION SYSTEMMay 1, 1998
57 days to decisionK980852 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k980852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 5, 1998
Decision date	May 1, 1998
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Karen E. Warden, M.E.B.E.
Location	Cleveland, OH, US
Contact	KAREN E WARDEN
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980852/> 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 21, 2026