FDA 510(k) Premarket Notification

K980852 GII SPINAL FIXATION SYSTEM

CLEARED

May 1, 1998
57 days to decision

K980852 · 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