

K000020 MODIFICATION TO ISOBAR SPINAL SYSTEM

Feb 3, 2000
 30 days to decision

K000020 · Product code: **MNH** · Orthopedic
 Source: <https://www.510kdatabase.net/k000020/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jan 4, 2000
Decision date	Feb 3, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Encore Orthopedics, Inc.
Location	Red Rock, TX, US
Contact	DEBBIE DE LOS SANTOS
510(k) history	85 submissions · 74 cleared · 1993-2004

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000020/> 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 20, 2026