FDA 510(k) Premarket Notification

K930891 SYNTHES (USA) UNIV SPINE ROD/SACRAL SCREW FIX SYST

CLEARED

Apr 29, 1994
431 days to decision

K930891 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k930891/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Feb 22, 1993
Decision date	Apr 29, 1994
Days to decision	431 days
Third-party review	No

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	DIANE C TIERNAN
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k930891/ 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 14, 2026