FDA 510(k) Premarket Notification

K922672 AUGMENT POSTERIOR SPINAL FIXATION SYSTEM

CLEARED

May 18, 1993
348 days to decision

K922672 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k922672/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jun 4, 1992
Decision date	May 18, 1993
Days to decision	348 days
Third-party review	No

APPLICANT

Company	**Sofamor Danek Mfg., Inc.**
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	23 submissions · 12 cleared · 1992-1995