FDA 510(k) Premarket Notification

K964159 CD SPINAL SYSTEM

CLEARED

Oct 16, 1997
365 days to decision

K964159 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k964159/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Oct 16, 1996
Decision date	Oct 16, 1997
Days to decision	365 days
Third-party review	No

APPLICANT

Company	**Sofamor Danek USA,Inc.**
Location	Memphis, TN, US
Contact	RICHARD W TREHARNE, PH.D.
510(k) history	41 submissions · 26 cleared · 1995-2000