FDA 510(k) Premarket Notification

K935113 J.B.S. IMPLANTABLE SPINAL FIXATION DEVICE

CLEARED

Oct 19, 1994
359 days to decision

K935113 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k935113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Oct 25, 1993
Decision date	Oct 19, 1994
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**J.B.S., S.A.**
Location	Foster City, CA, US
Contact	HARTMUT H LOCH
510(k) history	10 submissions · 6 cleared · 1994-1996