FDA 510(k) Premarket Notification

K012173 DEVICE MODIFICATION OF SILHOUETTE SPINDAL FIXATION SYSTEM

CLEARED

Sep 28, 2001
78 days to decision

K012173 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k012173/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jul 12, 2001
Decision date	Sep 28, 2001
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sulzer Spine-Tech**
Location	Minneapolis, MN, US
Contact	KRISTYN M BENSON
510(k) history	7 submissions · 7 cleared · 1999-2002