FDA 510(k) Premarket Notification

K002959 MODIFICATION TO ISOBAR SPINAL SYSTEM

CLEARED

Oct 16, 2000
24 days to decision

K002959 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k002959/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Sep 22, 2000
Decision date	Oct 16, 2000
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Encore Orthopedics, Inc.**
Location	Red Rock, TX, US
Contact	JOANNA DROEGE
510(k) history	85 submissions · 74 cleared · 1993-2004