FDA 510(k) Premarket Notification

K953076 TOWNLEY FACET/PEDICULAR SCREW PLATING SYSTEM

CLEARED

Feb 28, 1997
609 days to decision

K953076 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k953076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jun 30, 1995
Decision date	Feb 28, 1997
Days to decision	609 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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