FDA 510(k) Premarket Notification

K101765 KYPHON ANCHOR FACET SCREW SYSTEM

CLEARED

Oct 22, 2010
121 days to decision

K101765 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k101765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jun 23, 2010
Decision date	Oct 22, 2010
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Spine, LLC**
Location	Sunnyvale, CA, US
Contact	ERICA HOFFMAN
510(k) history	2 submissions · 2 cleared · 2010-2011