FDA 510(k) Premarket Notification

K100765 FIXPINE II SYSTEM

CLEARED

Jul 19, 2010
124 days to decision

K100765 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k100765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 17, 2010
Decision date	Jul 19, 2010
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dio Medical Co., Ltd.**
Location	Santa Fe Springs, CA, US
Contact	JOYCE BANG
510(k) history	7 submissions · 7 cleared · 2010-2017