FDA 510(k) Premarket Notification

K080058 TURBO PRIME IBD SYSTEM

CLEARED

Apr 16, 2008
98 days to decision

K080058 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k080058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 9, 2008
Decision date	Apr 16, 2008
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineselect, LLC**
Location	Apple Valley, MN, US
Contact	RICHARD JANSEN
510(k) history	2 submissions · 2 cleared · 2008-2014