FDA 510(k) Premarket Notification

K072791 ORACLE SPACER, OPAL SPACER

CLEARED

Dec 26, 2007
86 days to decision

K072791 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k072791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 1, 2007
Decision date	Dec 26, 2007
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes Spine**
Location	Paoli, PA, US
Contact	STACEY BONNELL
510(k) history	36 submissions · 32 cleared · 1995-2012