FDA 510(k) Premarket Notification

CLEARED

K081395 SOLITAIRE PEEK-OPTIMA ANTERIOR SPINAL SYSTEM

Jun 25, 2008
37 days to decision

K081395 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k081395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 19, 2008
Decision date	Jun 25, 2008
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine**
Location	Warsaw, IN, US
Contact	VIVIAN KELLY
510(k) history	19 submissions · 18 cleared · 2007-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081395/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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