

**K081917 DEPUY SPINE BENGAL, CONCORDE, COUGAR,
DEVEX AND LEOPARD SYSTEMS**May 22, 2009
323 days to decisionK081917 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k081917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 3, 2008
Decision date	May 22, 2009
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Spine, Inc.
Location	Raynham, MA, US
Contact	SHARON STAROWICZ
510(k) history	68 submissions · 67 cleared · 2004-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081917/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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