

K103228 PARAMOUNT R IBF DEVICEJan 5, 2011
64 days to decisionK103228 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k103228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 2, 2010
Decision date	Jan 5, 2011
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Theken Spine, LLC
Location	Akron, OH, US
Contact	DALE DAVISON
510(k) history	23 submissions · 23 cleared · 2007-2012

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