

**K083798 IMPIX ALIF LUMBAR IBF, IMPIX ALIF-D LUMBAR IBF,  
IMPIX TLIF LUMBAR IBF**

May 19, 2010  
513 days to decision

K083798 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k083798/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 22, 2008
Decision date	May 19, 2010
Days to decision	513 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea Technologies</b>
Location	Round Rock, TX, US
Contact	DONALD GUTHNER
510(k) history	14 submissions · 14 cleared · 2007-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k083798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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