

**K181591 Fixated Asfora BULLET CAGE® (FABC)**Sep 26, 2018  
100 days to decisionK181591 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k181591/>**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	Jun 18, 2018
Decision date	Sep 26, 2018
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Designs, LLC</b>
Location	Brandon, SD, US
Contact	Kristi Vondra
510(k) history	7 submissions · 7 cleared · 2000-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181591/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 22, 2026