

**K170676 HD Lumbar Interbody System**Jul 13, 2017  
129 days to decisionK170676 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k170676/>**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	Mar 6, 2017
Decision date	Jul 13, 2017
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hd Lifesciences, LLC</b>
Location	Stoneham, MA, US
Contact	Ian Helmar
510(k) history	3 submissions · 3 cleared · 2017-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170676/> 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 28, 2026