

**K180364 HD LifeSciences Cervical IBFD System**Jun 27, 2018  
135 days to decisionK180364 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k180364/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 12, 2018
Decision date	Jun 27, 2018
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hd Lifesciences, LLC</b>
Location	Stoneham, MA, US
Contact	John Sullivan
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/k180364/> 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