

K181115 CxHA PEEK Cervical IBF SystemJul 16, 2018
80 days to decisionK181115 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k181115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Apr 27, 2018
Decision date	Jul 16, 2018
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis, Inc.
Location	Salt Lake City, UT, US
Contact	Marshall McCarty
510(k) history	33 submissions · 32 cleared · 2004-2025

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