

K161407 Ascential IBD PEEKc SpacerJul 15, 2016
56 days to decisionK161407 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k161407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	May 20, 2016
Decision date	Jul 15, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Spine
Location	Allendale, NJ, US
Contact	Tina Mornak
510(k) history	74 submissions · 73 cleared · 2004-2026

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