

K181337 Sypher Spacer SystemSep 18, 2018
120 days to decisionK181337 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k181337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 21, 2018
Decision date	Sep 18, 2018
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biogenix, LLC
Location	Irvine, CA, US
Contact	Tim Bumbalough
510(k) history	8 submissions · 8 cleared · 2010-2024

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