

K191353 COMET Lumbar Interbody Fusion CageApr 14, 2020
329 days to decisionK191353 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k191353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 21, 2019
Decision date	Apr 14, 2020
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baui Biotech Co., Ltd.
Location	New Taipei City, TW
Contact	Jessy Lin
510(k) history	5 submissions · 5 cleared · 2017-2024

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