

K233075 “BioGend” Interbody Fusion System 001 CageMar 6, 2024
162 days to decisionK233075 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k233075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 26, 2023
Decision date	Mar 6, 2024
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biogend Therapeutics Co., Ltd.
Location	Taipei, TW
Contact	Chienpei Chen
510(k) history	1 submissions · 1 cleared · 2024-2024

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