

K180228 II-Type Intervertebral SpacerJan 11, 2019
350 days to decisionK180228 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k180228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 26, 2018
Decision date	Jan 11, 2019
Days to decision	350 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paonan Biotech Co., Ltd.
Location	Taipei, TW
Contact	Vivi Tsai
510(k) history	6 submissions · 6 cleared · 2017-2023

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