

K192044 4CIS Marlin PEEK ACIF CageDec 19, 2019
141 days to decisionK192044 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k192044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 31, 2019
Decision date	Dec 19, 2019
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Solco Biomedical Co., Ltd.
Location	Bethesda, MD, US
Contact	Hwi-geun Yu
510(k) history	17 submissions · 17 cleared · 2005-2024

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