

K190067 Velofix Interbody Fusion SystemFeb 4, 2019
20 days to decisionK190067 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k190067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jan 15, 2019
Decision date	Feb 4, 2019
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corporation
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	Jee-Ae Bang
510(k) history	23 submissions · 23 cleared · 2013-2022

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