

K202458 BonOs Inject, Pedicle screw kits, Cement pusherMay 18, 2021
264 days to decisionK202458 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k202458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Aug 27, 2020
Decision date	May 18, 2021
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osartis GmbH
Location	Dieburg, DE
Contact	Volker Stirnal
510(k) history	6 submissions · 6 cleared · 2019-2024

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