

K240856 Hip Spacer MoldsNov 20, 2024
237 days to decisionK240856 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k240856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Mar 28, 2024
Decision date	Nov 20, 2024
Days to decision	237 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Knee Spacer Molds; Shoulder Spacer Molds

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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