

**K193075 Osteo3 ZP Putty**Jun 9, 2020  
218 days to decisionK193075 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k193075/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Nov 4, 2019
Decision date	Jun 9, 2020
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sirakoss , Ltd.</b>
Location	Aberdeen, GB
Contact	Jordan Conway
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>PaxMed International, LLC</b>
Contact	Kevin A Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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