

K213111 MagnetOs granulesJan 10, 2022
108 days to decisionK213111 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k213111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 24, 2021
Decision date	Jan 10, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kuros Biosciences B.V
Location	Bilthoven, NL
Contact	Sonja van der Meer
510(k) history	12 submissions · 12 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Mehdi Kazemzadeh-Narbat

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

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