

K240621 Morpheus® MoldableApr 30, 2024
56 days to decisionK240621 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k240621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Mar 5, 2024
Decision date	Apr 30, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Agilon® Moldable

APPLICANT

Company	Biogennix, LLC
Location	Irvine, CA, US
Contact	Laura Jones
510(k) history	8 submissions · 8 cleared · 2010-2024

REGULATORY CONSULTANT

Consulting firm	Bruder Consulting & Venture Group
Contact	Scott Bruder

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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