

**K161996 0.5cc NanoFUSE, 1.0cc NanoFUSE, 2cc NanoFUSE,
5cc NanoFUSE, 10cc NanoFUSE**

Feb 16, 2017
212 days to decision

K161996 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k161996/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 19, 2016
Decision date	Feb 16, 2017
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amend Surgical, Inc.
Location	Alachua, FL, US
Contact	Robert Lane
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161996/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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