

K193487 Agilon StripMar 30, 2020
104 days to decisionK193487 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k193487/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Dec 17, 2019 |
| Decision date | Mar 30, 2020 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biogenix, LLC |
| Location | Irvine, CA, US |
| Contact | Timothy Bumbalough |
| 510(k) history | 8 submissions · 8 cleared · 2010-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193487/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026