

K040419 DYNAGRAFT IIMar 25, 2005
401 days to decisionK040419 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k040419/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Feb 18, 2004 |
| Decision date | Mar 25, 2005 |
| Days to decision | 401 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Isotis Orthobiologics, Inc. |
| Location | Bilthoven, NL |
| Contact | ELIANE SCHUTTE |
| 510(k) history | 10 submissions · 10 cleared · 2004-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040419/> 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 19, 2026