

K082338 POLYBONE GRANULE & BLOCKOct 16, 2008
63 days to decisionK082338 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k082338/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Aug 14, 2008 |
| Decision date | Oct 16, 2008 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kyung Won Medical Co., Ltd. |
| Location | Santa Fe Springs, CA, US |
| Contact | JUNG BAE BANG |
| 510(k) history | 4 submissions · 4 cleared · 2007-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082338/> 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 18, 2026