

**K004003 PRO OSTEON 200R WITH CALCIUM SULFATE,
MODELS 2RCS038, 2RCS050, 2RCS075, 2RCS10, 2RCS15,
2RCS20, 2RCS225, 2RCS30**Jul 19, 2001
206 days to decisionK004003 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k004003/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Filler, Bone Void, Calcium Compound (MQV) |
| Date received | Dec 25, 2000 |
| Decision date | Jul 19, 2001 |
| Days to decision | 206 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Interpore Cross Intl. |
| Location | Irvine, CA, US |
| Contact | LYNN M RODARTI |
| 510(k) history | 39 submissions · 38 cleared · 1998-2005 |

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