

K013534 SELF-COUNTERSINKING BONE SCREWDec 17, 2001
55 days to decisionK013534 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k013534/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Oct 23, 2001 |
| Decision date | Dec 17, 2001 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biomet Orthopedics, Inc. |
| Location | Warsaw, IN, US |
| Contact | SARA B SHULTZ |
| 510(k) history | 34 submissions · 34 cleared · 2000-2008 |

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