

**K951232 EXPANDED RANGE OF SUTURE SIZES OGDEN
ANCHORS: 7.4MM AND 5.5MM**Aug 25, 1995
158 days to decisionK951232 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k951232/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Mar 20, 1995 |
| Decision date | Aug 25, 1995 |
| Days to decision | 158 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | American Medical Electronics, Inc. |
| Location | Dallas, TX, US |
| Contact | MARY BIGGERS |
| 510(k) history | 14 submissions · 11 cleared · 1989-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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