FDA 510(k) Premarket Notification

# K010738 CANNULATED PLUS SCREW SYSTEM

**CLEARED**

Aug 1, 2001
142 days to decision

K010738 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k010738/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Mar 12, 2001 |
| Decision date | Aug 1, 2001 |
| Days to decision | 142 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Orthomatrix, Inc.** |
| Location | Walker, MI, US |
| Contact | BEN SHAPPLEY |
| 510(k) history | 8 submissions · 8 cleared · 1984-2001 |