

K112455 AIMING BLOCKS FOR VARIAX DISTAL RADIUS PLATESSep 22, 2011
28 days to decisionK112455 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k112455/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Aug 25, 2011 |
| Decision date | Sep 22, 2011 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Howmedica Osteonics Corp., Db a Stryker Orthopaedics |
| Location | Malwah, NJ, US |
| Contact | STEPHANIE FITTS |
| Website | https://www.stryker.com |
| 510(k) history | 31 submissions · 31 cleared · 2010-2026 |

Howmedica Osteonics Corp., Db a Stryker Orthopaedics is a medical device manufacturer based in Malwah, US. The company operates as part of Stryker, a global medical technology leader. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2010. 97% of submissions focus on Orthopedic devices, including joint replacement systems, knee implants, and hip components. The latest clearance in 2026 demonstrates continued regulatory activity and product innovation. Recent cleared devices include the Triathlon® Total Knee System with multi...

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Device record: <https://www.510kdatabase.net/k112455/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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