

**K112481 FIRST CHOICE DRUJ SYSTEM, PARTIAL HEAD
IMPLANT**Apr 9, 2012
224 days to decisionK112481 · Product code: **KXE** · Orthopedic
Source: <https://www.510kdatabase.net/k112481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Hemi-, Ulnar (KXE)
Date received	Aug 29, 2011
Decision date	Apr 9, 2012
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ascension Orthopedic
Location	Austin, TX, US
Contact	BRADLEY W STRASSER
510(k) history	7 submissions · 7 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026