

K233315 HipXpert and HipInsight SystemAug 8, 2024
314 days to decisionK233315 · Product code: **OSF** · Orthopedic
Source: <https://www.510kdatabase.net/k233315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patient Specific Manual Orthopedic Stereotaxic System (OSF)
Date received	Sep 29, 2023
Decision date	Aug 8, 2024
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgical Planning Associates, Inc.
Location	Boston, MA, US
Contact	Stephen Murphy
510(k) history	2 submissions · 2 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Hills Quality and Regulatory Services, LLC
Contact	Kellen Hills

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233315/> 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 13, 2026