

**K233148 Augment Off-Axis Instrument System**Mar 22, 2024  
177 days to decisionK233148 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k233148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 27, 2023
Decision date	Mar 22, 2024
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fix Surgical</b>
Location	Conshohocken, PA, US
Contact	Brian Karpinski
510(k) history	2 submissions · 2 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233148/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026