

K210533 Inset Reverse Total Shoulder SystemAug 20, 2021
177 days to decisionK210533 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k210533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Feb 24, 2021
Decision date	Aug 20, 2021
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shoulder Innovations, Inc.
Location	Holland, MI, US
Contact	Don Running
510(k) history	8 submissions · 8 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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