

K243643 restor3d Reverse Total Shoulder Arthroplasty SystemMay 19, 2025
174 days to decisionK243643 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k243643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 26, 2024
Decision date	May 19, 2025
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Restor3d
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	11 submissions · 11 cleared · 2020-2025

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