

K161189 Integra TITAN Reverse Shoulder SystemAug 25, 2016
120 days to decisionK161189 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k161189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Apr 27, 2016
Decision date	Aug 25, 2016
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	William Garzon
510(k) history	65 submissions · 65 cleared · 2004-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161189/> 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 15, 2026