

K190588 Integra TITAN Reverse Shoulder SystemDec 2, 2019
270 days to decisionK190588 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k190588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 7, 2019
Decision date	Dec 2, 2019
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190588/> 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