

K192365 Shoulder Innovations Total Shoulder SystemNov 29, 2019
91 days to decisionK192365 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k192365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Aug 30, 2019
Decision date	Nov 29, 2019
Days to decision	91 days
Third-party review	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

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