

**K191247 SmartSPACE Shoulder System**Nov 15, 2019  
190 days to decisionK191247 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k191247/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	May 9, 2019
Decision date	Nov 15, 2019
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Techmah Medical, LLC</b>
Location	Knoxville, TN, US
Contact	Mohamed R. Mahfouz
510(k) history	3 submissions · 3 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191247/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026