

K190136 Fusion Silastic SystemOct 21, 2019
265 days to decisionK190136 · Product code: **KWH** · Orthopedic
Source: <https://www.510kdatabase.net/k190136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Constrained, Polymer (KWH)
Date received	Jan 29, 2019
Decision date	Oct 21, 2019
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fusion Orthopedics, LLC
Location	Mesa, AZ, US
Contact	Eli Jacobson
510(k) history	11 submissions · 11 cleared · 2016-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190136/> 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 27, 2026