

K183054 SYNMesh SystemMay 23, 2019
202 days to decisionK183054 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k183054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Nov 2, 2018
Decision date	May 23, 2019
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Synthes Spine
Location	Raynham, MA, US
Contact	Michelle Hughes
510(k) history	2 submissions · 2 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183054/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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