

K183197 PYRAMESH™ Implant SystemApr 4, 2019
136 days to decisionK183197 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k183197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Nov 19, 2018
Decision date	Apr 4, 2019
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	ANkit K. Shah
510(k) history	170 submissions · 159 cleared · 2000-2026

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