

K231147 Hammerdesis™ Interphalangeal Fusion SystemSep 14, 2023
146 days to decisionK231147 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k231147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Apr 21, 2023
Decision date	Sep 14, 2023
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Intelivation
Location	Plymouth Meeting, PA, US
Contact	David Posillico
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Rqmis
Contact	Barry Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231147/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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