

K211703 Insignia Hip StemAug 16, 2021
74 days to decisionK211703 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k211703/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Jun 3, 2021
Decision date	Aug 16, 2021
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Orthopaedics
Location	Malwah, NJ, US
Contact	Valerie Giambanco
510(k) history	24 submissions · 24 cleared · 2004-2021

REGULATORY CONSULTANT

Consulting firm	Howmedica Osteonics Corp. A.K.A. Stryker Orthopaedics
Contact	Gregg Ritter

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

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