

K243839 Alteon® HA Femoral StemsMar 10, 2025
87 days to decisionK243839 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k243839/>**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	Dec 13, 2024
Decision date	Mar 10, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	Pedro Ravelo
510(k) history	186 submissions · 174 cleared · 1986-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243839/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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