

K171249 Entrada™ hip stem

Aug 24, 2017
118 days to decision

K171249 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k171249/>

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	Apr 28, 2017
Decision date	Aug 24, 2017
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Development Corporation
Location	Draper, UT, US
Contact	Drew Weaver
510(k) history	14 submissions · 14 cleared · 2015-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171249/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026