

K202705 Prime and DYNASTY® Additive Manufacturing ShellsAug 20, 2021
338 days to decisionK202705 · Product code: **OQG** · Orthopedic
Source: <https://www.510kdatabase.net/k202705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hip Prosthesis, Semi-constrained, Cemented, Metal/polymer, + Additive, Porous, Uncemented (OQG)
Date received	Sep 16, 2020
Decision date	Aug 20, 2021
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microport Orthopedics, Inc.
Location	Arlington, TN, US
Contact	Gillen Gonzales
510(k) history	37 submissions · 37 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202705/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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