FDA 510(k) Premarket Notification

CLEARED

K202705 Prime and DYNASTY® Additive Manufacturing Shells

Aug 20, 2021
338 days to decision

K202705 · 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