

K203472 KMTI Hip Replacement SystemApr 2, 2021
128 days to decisionK203472 · Product code: **OQG** · Orthopedic
Source: <https://www.510kdatabase.net/k203472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hip Prosthesis, Semi-constrained, Cemented, Metal/polymer, + Additive, Porous, Uncemented (OQG)
Date received	Nov 25, 2020
Decision date	Apr 2, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kyocera Medical Technologies, Inc.
Location	Redlands, CA, US
Contact	Anthony DeBenedictis
510(k) history	15 submissions · 15 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	MEDlcept, Inc.
Contact	Sharyn Orton

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203472/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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