

K221048 Episealer Patellofemoral SystemDec 23, 2022
259 days to decisionK221048 · Product code: **KRR** · Orthopedic
Source: <https://www.510kdatabase.net/k221048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femoral, Semi-constrained, Cemented, Metal/polymer (KRR)
Date received	Apr 8, 2022
Decision date	Dec 23, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Episurf Medical, Inc.
Location	New York, NY, US
Contact	Katarina Flodstrom
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Hollace Saas Rhodes

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

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