

K212307 BC Reflex Uni Knee SystemOct 12, 2021
81 days to decisionK212307 · Product code: **HSX** · Orthopedic
Source: <https://www.510kdatabase.net/k212307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jul 23, 2021
Decision date	Oct 12, 2021
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bodycad Laboratories, Inc.
Location	Quebec City, CA
Contact	Nadine Adia
510(k) history	16 submissions · 16 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	BioVera, Inc.
Contact	Robert A Poggie

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

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Device record: <https://www.510kdatabase.net/k212307/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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