

**K211895 BC Reflex Uni Knee System**Aug 20, 2021  
60 days to decisionK211895 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k211895/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jun 21, 2021
Decision date	Aug 20, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>BioVera, Inc.</b>
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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