FDA 510(k) Premarket Notification

K212307 BC Reflex Uni Knee System

CLEARED

Oct 12, 2021
81 days to decision

K212307 · 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