

K193122 Biocore9 Humeral Resurfacing SystemMay 15, 2020
185 days to decisionK193122 · Product code: **HSD** · Orthopedic
Source: <https://www.510kdatabase.net/k193122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Nov 12, 2019
Decision date	May 15, 2020
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biocore9, LLC
Location	Whippany, NJ, US
Contact	Stan Matlak
510(k) history	3 submissions · 3 cleared · 2020-2022

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