

K201219 Biocore9 Femoral Head Resurfacing ComponentJan 19, 2021
258 days to decisionK201219 · Product code: **KXA** · Orthopedic
Source: <https://www.510kdatabase.net/k201219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Femoral, Resurfacing (KXA)
Date received	May 6, 2020
Decision date	Jan 19, 2021
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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