

**K222820 BRM TOOL Screws, BIOPLAN Subtalar Implant**Dec 16, 2022  
88 days to decisionK222820 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k222820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 19, 2022
Decision date	Dec 16, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brm Extremities</b>
Location	Milano, MI, US
Contact	Lisa Fazzini
510(k) history	2 submissions · 2 cleared · 2020-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Timothy Sutton

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222820/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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