

**K191319 Dunamis Fixation Button System**Aug 29, 2019  
106 days to decisionK191319 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k191319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 15, 2019
Decision date	Aug 29, 2019
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dunamis, LLC</b>
Location	Greenville, AL, US
Contact	Prithviraj Chavan
510(k) history	6 submissions · 6 cleared · 2015-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Hollace Rhodes

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/k191319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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