

K192428 AFX Femoral Implant with InserterOct 5, 2019
30 days to decisionK192428 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k192428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 5, 2019
Decision date	Oct 5, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cayenne Medical
Location	Scottsdale, AZ, US
Contact	Shima Hashemian
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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