

K161033 AFX™ Femoral Implant With InserterAug 3, 2016
112 days to decisionK161033 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k161033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 13, 2016
Decision date	Aug 3, 2016
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cayenne Medical, Inc.
Location	San Diego, CA, US
Contact	SHIMA HASHEMIAN
510(k) history	22 submissions · 22 cleared · 2006-2018

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