

K162125 MALUC™ Total Hip Arthroplasty SystemMay 10, 2017
282 days to decisionK162125 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k162125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Aug 1, 2016
Decision date	May 10, 2017
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Surgtech, Inc.
Location	Westlake, OH, US
Contact	Xuegong Yu
510(k) history	6 submissions · 6 cleared · 2016-2019

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