

K140075 U2 FEMORAL COMPONENT, CR, POROUS COATED

Jun 13, 2014
151 days to decision

K140075 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k140075/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Jan 13, 2014
Decision date	Jun 13, 2014
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	United Orthopedic Corp.
Location	Hsinchu, TW
Contact	FANG-YUAN HO
510(k) history	20 submissions · 20 cleared · 2000-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k140075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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