

K053505 REGENEREX ULTRA POROUS CONSTRUCT-FEMORAL AND TIBIAL KNEE AUGMENTSAug 14, 2006
241 days to decisionK053505 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k053505/>**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	Dec 16, 2005
Decision date	Aug 14, 2006
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Manufacturing, Inc.
Location	Warsaw, IN, US
Contact	TRACY B JOHNSON
510(k) history	32 submissions · 32 cleared · 1999-2013

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