

K083782 REGENEREX PATELLA COMPONENTSApr 3, 2009
105 days to decisionK083782 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k083782/>**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 19, 2008
Decision date	Apr 3, 2009
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Manufacturing Corp
Location	Warsaw, IN, US
Contact	SUSAN ALEXANDER
510(k) history	93 submissions · 93 cleared · 2004-2023

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