

**K103598 PROPHECY PRE-OPERATIVE NAVIGATION
ALIGNMENT GUIDES**Oct 17, 2011
313 days to decisionK103598 · Product code: **MBH** · Orthopedic
Source: <https://www.510kdatabase.net/k103598/>**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 8, 2010
Decision date	Oct 17, 2011
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wrightmedicaltechnologyinc
Location	Arlington, TN, US
Contact	SARAH HOLTGREWE
510(k) history	302 submissions · 291 cleared · 1993-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103598/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026