

**K212839 Opulent TiNbN Coated Knee**Nov 16, 2021  
70 days to decisionK212839 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k212839/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Sep 7, 2021
Decision date	Nov 16, 2021
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meril Healthcare Pvt. , Ltd.</b>
Location	Muktanand Marg, Chala, Vapi, IN
Contact	Neelam Desai
510(k) history	7 submissions · 7 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212839/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026