

**K183472 DePuy Synthes Porous Polyethylene Implants and Titanium Wires Portfolio – MR Conditional**Mar 13, 2019  
89 days to decisionK183472 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183472/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Dec 14, 2018
Decision date	Mar 13, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Synthes USA Products, LLC</b>
Location	West Chester, PA, US
Contact	Fredy Varela
510(k) history	60 submissions · 60 cleared · 2010-2022

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183472/> 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 June 28, 2026