

K140462 MATRIXNEURO PREFORMED MESH (PART OF THE MATRIXNEURO CRANIAL PLATING SYSTEM)Jun 13, 2014
109 days to decisionK140462 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k140462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Feb 24, 2014
Decision date	Jun 13, 2014
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	ALAN T HALEY
510(k) history	60 submissions · 60 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140462/> 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 June 6, 2026