

**K231834 VSP PEEK Cranial Implant**Apr 4, 2024  
287 days to decisionK231834 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k231834/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Jun 22, 2023
Decision date	Apr 4, 2024
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3D Systems, Inc.</b>
Location	Golden, CO, US
Contact	Ashley Dawson
Website	<a href="http://www.3dsystems.com/">http://www.3dsystems.com/</a>
510(k) history	11 submissions · 11 cleared · 2016-2025

3D Systems, Inc. is a healthcare technology company specializing in personalized medical device solutions. The company operates with a manufacturing facility in Golden, Colorado, and serves orthopedic, neurology, and radiology specialties through advanced 3D printing and imaging technologies. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2016. Orthopedic devices represent the dominant category, including ankle and cranial implant systems. The latest clearance in 2025 confirms continued regulatory activity and product in...