

**K200047 ExcelsiusGPS Cranial 1.0 Module**Jul 10, 2020  
183 days to decisionK200047 · Product code: **OLO** · Neurology  
Source: <https://www.510kdatabase.net/k200047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 9, 2020
Decision date	Jul 10, 2020
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Globus Medical, Inc.</b>
Location	Audubon, PA, US
Contact	Jennifer Antonacci
Website	<a href="https://www.globusmedical.com">https://www.globusmedical.com</a>
510(k) history	172 submissions · 169 cleared · 2003-2026

Globus Medical, Inc. is a publicly traded orthopedic medical device company headquartered in Audubon, Pennsylvania. The company designs, develops, and commercializes products enabling surgeons to promote healing in patients with musculoskeletal disorders. Globus Medical has received FDA 510(k) clearances from total submissions since its first clearance in 2003. The company's regulatory portfolio is dominated by orthopedic devices, representing 98% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued innovation and market presenc...

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Device record: <https://www.510kdatabase.net/k200047/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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