

**K130389 MAYFIELD INFINITY XR2 SKULL CLAMP**Apr 23, 2013  
67 days to decisionK130389 · Product code: **HBL** · Neurology  
Source: <https://www.510kdatabase.net/k130389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	Feb 15, 2013
Decision date	Apr 23, 2013
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integra LifeSciences Corporation</b>
Location	Planisboro, NJ, US
Contact	JANET KAY
510(k) history	65 submissions · 65 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130389/> 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 15, 2026