

**K123633 TRS CRANIAL BONE VOID FILLER(TRS C-BVF)**Aug 16, 2013  
266 days to decisionK123633 · Product code: **GXR** · Neurology  
Source: <https://www.510kdatabase.net/k123633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Nov 23, 2012
Decision date	Aug 16, 2013
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tissue Regeneration Systems, Inc.</b>
Location	Kirkland, WA, US
Contact	JIM FITZSIMMONS
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123633/> 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 8, 2026