

**K192310 Flap Fixator, Burr Hole Cover**Jun 3, 2020  
282 days to decisionK192310 · Product code: **GXR** · Neurology  
Source: <https://www.510kdatabase.net/k192310/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Aug 26, 2019
Decision date	Jun 3, 2020
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ossaware Biotech Co., Ltd.</b>
Location	Shenkang Hsiang, TW
Contact	Meng Feng Huang
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192310/> 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 20, 2026