

K221606 Absorbable Cranial Flap Fixation SystemNov 21, 2023
537 days to decisionK221606 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k221606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Jun 2, 2022
Decision date	Nov 21, 2023
Days to decision	537 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chendu Medart Medical Scientific Co., Ltd.
Location	Chengdu, CN
Contact	Huaping Ran
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Joyce Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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