

K170368 Sterile NS SystemSep 11, 2017
217 days to decisionK170368 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k170368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Feb 6, 2017
Decision date	Sep 11, 2017
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jeil Medical Corporation
Location	Deer Field, IL, US
Contact	Seungyong Lee
510(k) history	53 submissions · 53 cleared · 2002-2026

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