

K182425 Universal Mesh - SterileNov 6, 2018
61 days to decisionK182425 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k182425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Sep 6, 2018
Decision date	Nov 6, 2018
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Leibinger GmbH & Co KG
Location	Freiburg Im Breisgau, DE
Contact	Gregory Gohl
510(k) history	21 submissions · 21 cleared · 2009-2026

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