

K202694 Vycor Medical Viewsite Brain Access System (“VBAS”) and VBAS with Alignment Clip (“VBAS AC”) (together the “VBAS Family”)

Jan 14, 2021
120 days to decision

K202694 · Product code: **GZT** · Neurology
Source: <https://www.510kdatabase.net/k202694/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, Self-retaining, For Neurosurgery (GZT)
Date received	Sep 16, 2020
Decision date	Jan 14, 2021
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vycor Medical, Inc.
Location	Boca Raton, FL, US
Contact	Theo Novak
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultant, Inc.
Contact	Maria Griffin

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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Device record: <https://www.510kdatabase.net/k202694/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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