U.S. Food and Drug Administration

Center for Devices and Radiological Health (CDRH)

Date: September 5, 2025

Subject: Major Deficiency Letter – PMA P240456

Sponsor: BioMed Solutions, LLC

Device: NeuroGuide Implant System

Submission: Premarket Approval Application (PMA)

Dear Dr. Alex Carter,

We have reviewed your PMA P240456 for the NeuroGuide Implant System intended for neuromodulation in patients with refractory epilepsy. Upon review, we have identified the following deficiencies.

Your application is on hold pending the requested information. A complete response is due within 180 days.

Major Deficiencies

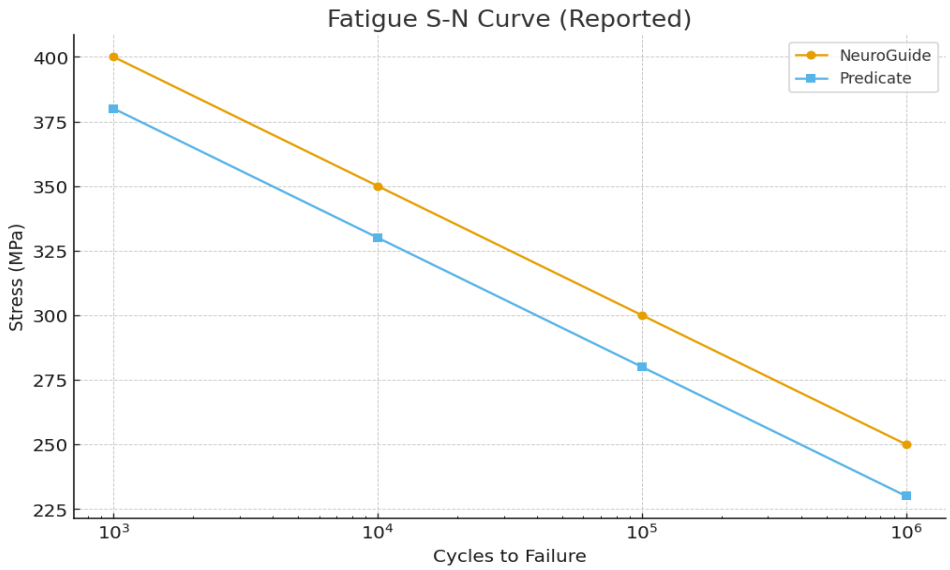
1. Clinical Data – Comparative Outcomes

You submitted a 120-patient pivotal trial comparing NeuroGuide to standard of care. However, data presentation was incomplete. The table below summarizes adverse event reporting (from Module 6). Please provide missing stratified analyses (e.g., age groups, concomitant AED use).

Adverse Event	NeuroGuide (n=60)	Standard of Care (n=60)
Headache	12 (20%)	8 (13%)
Implant site infection	4 (7%)	0 (0%)
Seizure worsening	6 (10%)	10 (17%)
Device migration	2 (3%)	—

2. Bench Testing – Fatigue Curve

You provided fatigue testing data, but the figure was low resolution. Please provide the original datasets and high-quality figures. Below is a placeholder representation of your reported S-N fatigue curve (Figure 3).



Additional Considerations

Editorial corrections to labeling will be communicated at the time of final review. Below is a summary of IFU inconsistencies identified.

Section	Reported Instruction	FDA Comment
4.2 Cleaning	Rinse with warm water	Specify validated detergent and parameters
6.1 Implant	Fixation with two screws	Clarify torque range and compatible screw sizes