Neurological Devices Panel of the Medical Devices Advisory Committee Meeting

June 3 and 4, 2021
FDA Virtual Meeting
10903 New Hampshire Avenue
Silver Spring, MD 20993

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the Neurological Devices Advisory Panel for the purposes of obtaining recommendations about the classification of neurological and physical medicine devices.

FDA is holding this panel meeting to obtain input on the risks and benefits of neurological and physical medicine devices for use. The Panel will be asked to recommend to FDA whether these devices should be classified into Class I (subject only to General Controls) or Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.

AGENDA – Neurological Devices (Day 1)

9:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	Panel Chair
9:15 a.m.	Conflict of Interest Statement	Designated Federal Officer
9:20 a.m.	Open Public Hearing	
10:20 a.m.	Classification and Reclassification Overview	Megha Reddy
10:30 a.m.	**FDA Presentation- MLY – Vapocoolant device**	Ozell Sanders, PhD, MS
11:00 a.m.	Panel Deliberations- Q & A	
11:30 a.m.	*LUNCH*	
12:30 p.m.	**FDA Presentation- MVV – Acupressure device**	Mary (Molly) Keszler, MD, FAAPMR
1:30 p.m.	Panel Deliberations- Q & A	
2:30 p.m.	**FDA Presentation- BWK – Electro-acupuncture stimulator**	Robert Stefani, PhD
3:30 p.m.	Panel Deliberations- Q & A	
4:30 p.m.	**Summary of Day (optional)**	
4:45 p.m.	Proceedings Adjourned	

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AGENDA – Neurological Devices Panel (Day 2)

9:00 a.m.	Call to Order, Opening Remarks & Introduction of the Committee	Panel Chair
9:10 a.m.	Conflict of Interest Statement	Designated Federal Officer
9:20 a.m.	Classification and Reclassification Overview	Megha Reddy
9:30 a.m.	**FDA Presentation- LQD – Attention task performance recorder**	Mohua Choudhury
10:00 a.m.	Panel Deliberations- Q & A	Panel Chair
10:30 a.m.	**FDA Presentations- LDK – Optical contour sensing device**	Kiyana Weatherspoon
11:00 a.m.	Panel Deliberations- Q & A	
12:00 p.m.	**Lunch**	
1:00 p.m.	**FDA Presentation- LXM – Plunger-like joint manipulator**	Kaitlin Olsen, MS
2:00 p.m.	Panel Deliberations- Q & A	
3:00 p.m.	FDA Summation	
3:30 p.m.	Proceedings Adjourned	