

# Bellabee

16192 Coastal Highway, 19958 Lewes, County of Sussex, Delaware

## **Bellabee, wearable headband**

Product classification No.1/2019

Devices like Bellabee headband have been ruled "general wellness" devices by the **FDA**.  
(*General Wellness: Policy for Low-Risk Devices Guidance for Industry and Food and Drug Administration Staff Document issued on September 27, 2019. Document originally issued on July 29, 2016.*)

### **This is a category that the FDA has defined for the purposes of:**

- relaxation or stress management,
- mental acuity,
- sleep management.

### **The following are examples of this category of general wellness claims:**

- promote relaxation or manage stress;
- increase, improve, or enhance the flow of qi "energy";
- improve mental acuity, instruction following, concentration, problem-solving, multitasking resource management, decision-making, logic, pattern recognition, or eye-hand coordination;
- enhance learning capacity;
- promote sleep management, such as to track sleep trends;

### **Bellabee promotes being able to help to ease symptoms of:**

- insomnia
- stress
- lack of concentration
- anxiety
- inability to calm down at ease
- getting into a meditation zone faster
- reducing the heartbeat

Bellabee, Inc.

Urban BUTINAR, CEO

Austin, 2019/09/29