



Authorization and Evaluation Division
7435 Oakland Mills Rd
Columbia MD 21046-1609
USA

RE: Class II Permissive Change, FCC ID: 2BAXD-E02-0

Date: March 5, 2025

To Whom It May Concern,

Bluewind Medical Ltd. requests Class II Permissive change for device FCC ID: 2BAXD-E02-0. The E03 wearable device is a part of the Revi neurostimulation system. It provides wireless power for the neurostimulator implant and controls its operation. Submitted here are materials for your consideration in determining the Class II permissive change.

The E03 wearable device is intended to replace the previously approved revision. The changes performed with respect to the previously approved revision are:

1. A larger capacity battery is used to power the wearable device. The battery housing is also designed to allow battery replacement.
2. End of life electronic components have been replaced with more modern components
3. Internal PCB layouts was modified to improve reliability, testability and simplify components and high-level device assembly.
4. Mechanical changes supporting better manufacturability and support for the new board design
5. Modification of the user interface
6. List of important changes and their detailed changes were added in a separate file named "E03 ECU Detailed Changes"
7. The BLE Module LBCA2HNZY-711 from Murata electronics with WSM-BL241-ADA-008 FCC ID VPYLBZY that have an "End-of-Life" notice, so we replaced it with the recommended module from the same manufacture, which has almost pin to pin compatibility and the same form factor. Please see more details in the "E03 ECU Detailed Changes" file.

The power amplifier RF level of the transmitting carrier waveform and its modulation were not changed.

The E03 wearable changes do not affect the intended use of the device, nor do they change the treatment parameters and the level of emission and meet all the requirements of the waiver under which the original device has been approved. Moreover, the waiver itself states that it is applicable to future devices (such as the E03). Since there is no effect on the levels of the emission, and they are within those allowed by the waiver PAG is not applicable.

Sincerely yours,
Yigal Elisha

A handwritten signature in black ink, appearing to read "Yigal Elisha", with a stylized flourish at the end.