Attention:
Application Examiner

Re: Justification required per 47 CFR 15.19(a)(5)

Applicant: Neuros Medical, Inc.

FCC ID: 2BATK601

To whom it may concern,

The product (Altius IPG) is an Active Implantable device. It is packaged and sterilized. The packaging system of the product ensures that it remains sterile until is delivered to a healthcare facility where it may then be implanted in someone. Therefore, it is impractical to apply the language required by 47 CFR 15.19(a)(3) on the Altius IPG.

Once implanted in the patient, the label and packaging is then disposed of by the healthcare facility and the patient never sees the packaging of the Altius IPG. Therefore, it is impractical to apply the language required by 47 CFR 15.19(a)(3) on the packaging of the Altius IPG.

The User Manual, Neuros Document LB-0196 (Altius® Direct Electrical Nerve Stimulation System Patient Manual) does contain the language required by 47 CFR 15.19(a)(3). This language does meet the standard and its intent of informing the user.

Sincerely,

Raymond M Zackowski
Principal Systems Engineer
Neuros Medical, Inc.