Bravo Reflux Capsule Identification of equipment according to FCC section 2.925(f)

The FCC identifier and label will not be placed on the device itself for two reasons: (i) the Bravo Capsule is so small that placing the label on it is impracticable; and (ii) Bravo Delivery System is single use device and once the package is opened the capsule should be activated and attached to the esophagus of a patient, therefore having the label on the Delivery Unit or the Capsule would be of little use. Consistent with FCC 47 CFR § 2.925(f) and the accompanying note ("a device intended to be implanted within the body of a . . . person would probably require an alternate method of identification"), the Applicant proposes, as an alternative method of affixing the label, to affix it to the Bravo Delivery System's packaging as shown below and in the User's Manual, which is provided as a separate attachment accompanying the application.

The Bravo Reflux Capsule is packaged where FGS-0636 include 1 unit of Bravo delivery and capsule device while package of FGS-0635 include 5 units same exact to the one in FGS-0636 in a 5-pack box as presented below: