July 17, 2020

Victor Nunes
QMed Innovations
1005 Aquidneck Ave, Unit 1N
Middletown, RI 02842

Re: Quest Regulatory Assessment

Dear Victor,

The Quest Product was evaluated to determine if it meets the definition of a medical device. Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

The Quest product is an electronic asset tag that attaches to the exterior of an instrument tray and provides daily information regarding the location of instrument sets, or assets. The Quest product is not recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, is not intended to diagnose, treat, prevent, cure or mitigate any disease or condition and is not intended to affect the structure or any function of the body of man or other animals. Therefore, based on the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act, the Quest product is not a medical device when used to locate or track instrument trays.

The Quest Product is not in the scope of ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and Testing because it is not a medical device nor does it come in contact with the instruments in the trays.

The Quest Product that is attached externally to an instrument case is constructed of Radel® R 5100 and secured with 316 stainless steel rivets. The Radel® R 5100 case is sealed to prevent ingress and egress of fluid between the housing and external environment. Testing has shown that there are no leachable contaminates from the Radel® R 5100 housing. All engineering testing has been confirmed and is contained in the Design History File. Both Radel® R 5100 and 316 SS have a well-established history for use in medical devices in numerous applications.

Based on the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act, the Quest product is not a medical device. Per ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and Testing Devices biocompatibility testing is not required for Quest.

Sincerely,

SKIP FARINHA

Albert “Skip” Farinha
Principal
Strategic Device Solutions LLC