



Q30 Innovations, LLC  
257 Riverside Avenue  
Westport, CT 06880

October 19, 2017

Via Email

Dr. Greg Myer  
Cincinnati Children's Hospital Medical Center  
3333 Burnet Ave, MLC 10001  
Cincinnati, OH 45229

Re: Clarification of FDA Risk Determination for  
Usability and Tolerability Studies of the Q-Collar

Dear Dr. Myer:

Q30 Sports Science, LLC has agreed to sponsor usability and tolerability studies of a jugular vein compression device known as the Q-Collar. Through these studies, we hope to gather additional information concerning the experience of users wearing the Q-Collar during athletic training and competitive sports activities as a proxy for military personnel who may wear the Q-Collar in training and combat situations. We also hope to test the Q-Collar with military academy cadets and active duty personnel, if possible. We expect to study different designs and prototypes of the Q-Collar to further improve the device.

This letter is intended to inform you that the Q-Collar is still considered an investigational medical device that has not yet received clearance from the US Food and Drug Administration (the "FDA"). However, in response to a determination request submitted to the FDA, on December 28, 2016, the FDA determined that the Q-Collar is "nonsignificant risk (NSR) device." This risk determination is consistent with the decision of your Human Subjects Institutional Review Board's determination non-significant risk with your studies at Cincinnati Children's. Accordingly, it is my understanding that investigational device exemption ("IDE") applications to the FDA are not required to be submitted or approved by the FDA prior to the commencement of a study. NSR studies of the Q-Collar can be undertaken provided that the requirements set forth in 21 CFR 812.2(b) are followed. For example, the Collar must be labeled "Investigational Use" and the study must be performed with the approval of an institutional review board with the consent of each subject, monitoring and record retention. Provided these "abbreviated requirements" are followed, in my opinion, CCHMC can continue to perform human studies of the Q-Collar.

Thank you for your continued interest in evaluating the Q-Collar for use by athletes and military personnel. Please do not hesitate to contact me directly with questions or concerns.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Gary A. Greene', written over a horizontal line.

Gary A. Greene,  
General Counsel