February 26, 2021

Q30 Sports Science, LLC
℅ Bob Peterson
Principal Consultant
Halloran Consulting Group, Inc.
266 Summer Street, 8th Floor
Boston, Massachusetts 02210

Re: DEN200017
Trade/Device Name: Q-Collar
Regulation Number: 21 CFR 890.3050
Regulation Name: External compression device for internal jugular vein compression
Regulatory Class: Class II
Product Code: QNX
Dated: March 18, 2020
Received: March 19, 2020

Dear Bob Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Q-Collar, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The Q-Collar is a non-invasive device intended to be worn around the neck of athletes aged 13 years and older during sports activities to aid in the protection of the brain from effects associated with repetitive sub-concussive head impacts.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Q-Collar, and substantially equivalent devices of this generic type, into Class II under the generic name external compression device for internal jugular vein compression.

FDA identifies this generic type of device as:

> **External compression device for internal jugular vein compression**. An external compression device for internal jugular vein compression is a non-invasive device that is intended to increase intracranial venous pressure to reduce the occurrence of specific changes in the brain following head impacts.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 19, 2020, FDA received your De Novo requesting classification of the Q-Collar. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Q-Collar into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Q-Collar can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are syncope due to excessive compression, use error, interference with other equipment, or ineffective treatment leading to impact-related trauma or injury, and adverse tissue reaction. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Syncope due to excessive compression	Human factors testing Non-clinical performance testing Labeling
Use error, interference with other equipment, or ineffective treatment leading to impact-related trauma or injury	Human factors testing Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the External compression device for internal jugular vein compression is subject to the following special controls:

Special Controls
(1) The patient-contacting components of the device must be demonstrated to be biocompatible. (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following: i. Compression testing; and

Special Controls

ii. Durability testing over the labeled use life.

(3) Human factors and usability testing must demonstrate that users can correctly use the device, including:
   i. Confirming the proper size and fit of the device; and
   ii. Understanding the device labeling, including the warning that the device does not prevent head injury and medical treatment should be sought following head injury.

(4) Labeling must include the following:
   i. A warning that the device does not replace, and should be worn with, other protective sports equipment associated with specific sports activities, such as helmets and shoulder pads.
   ii. A warning that the device should not be worn if it interferes with other existing protective equipment.
   iii. A warning that users should avoid head and neck impacts to the extent possible.
   iv. A warning that serious harm can result from persistent, excessive pressure on the neck due to incorrect device size and fit.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the External compression device for internal jugular vein compression they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Kenneth Morabito at 301-796-3807.

Sincerely,

Nina C. Mezu-nwaba -S3

CAPT Nina Mezu-Nwaba, PharmD, MPH, MSc
Deputy Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health