U.S. Department of Homeland Security
U.S. Customs and Border Protection
National Commodity Specialist Division
One World Trade Center, Suite 51.201
New York, NY 10007

U.S. Customs and Border Protection

N356618

December 19, 2025

CLA-2-OT:RR:NC:N3:135

CATEGORY: Classification

TARIFF NO.:

Craig Lewis
Hogan Lovells US LLP
555 13th St. NW
Washington, DC 20004

RE: The eligibility of AUVI-Q's Electronic Prompt System for preferential tariff treatment under the Nairobi Protocol from Thailand

Dear Mr. Lewis:

In your letter dated December 2, 2025, you requested a tariff classification ruling on behalf of your client, Kaleo, Inc. The samples were received, examined, and disposed of.

The Electronic Prompt System is designed for incorporation in the AUVI-Q (epinephrine injection, USP), a compact auto-injector that provides gas-powered injection of epinephrine and automatic needle retraction. The Electronic Prompt System consists of a miniature speaker, battery contact arm, flexible circuit board, voice microchip, stacked batteries, red and green light emitting diodes ("LEDs"), tear-through switches, and an electronics cover designed to fit with the housing of the AUVI-Q. It provides audible cues for use in the form of voice instructions and beeps, as well as providing visual cues in the form of red and green blinking LEDs. The purpose of the Electronic Prompt System is to assist in guiding the AUVI-Q user, whether the patient or a third-party, through the use of the AUVI-Q in administering a life-saving dose of epinephrine during a severe allergic reaction. The system assists the user in locating certain components and the audible instructions prompt the user to take specific actions (like removing the red safety guard) or to wait to take an action (including how long to hold the device in place during the injection process).You state that the Electronic Prompt System is specially designed for incorporation in the AUVI-Q; it cannot be used with or incorporated into any other article. The Electronic Prompt System is imported and incorporated with the unfinished AUVI-Q in the United States to create the assembled combination product. You also state that the AUVI-Q is a prescription-only epinephrine delivery device for immediate emergency treatment of individuals experiencing type I allergic reactions, including anaphylaxis, triggered by allergens such as pollen, foods, or insect stings.

In your submission you requested consideration of a secondary classification under 9817.00.96, Harmonized Tariff Schedule of the United Sates (HTSUS), which applies to articles and parts and accessories of articles specifically designed or adapted for the use or benefit of the permanently or chronically physically or mentally handicapped.

Subheading 9817.00.96, HTSUS, covers: "Articles specially designed or adapted for the use or benefit of the blind or other physically or mentally handicapped persons; parts and accessories (except parts and accessories of braces and artificial limb prosthetics) that are specially designed or adapted for use in the foregoing articles . . . Other." The term "blind or other physically or mentally handicapped persons" includes "any person suffering from a permanent or chronic physical or mental impairment which substantially limits one or more major life activities, such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, or working." U.S. Note 4(a), Subchapter XVII, Chapter 98, HTSUS. Subheading 9817.00.96, HTSUS, excludes "(i) articles for acute or transient disability; (ii) spectacles, dentures, and cosmetic articles for individuals not substantially disabled; (iii) therapeutic and diagnostic articles; or, (iv) medicine or drugs." U.S. Note 4(b), Subchapter XVII, Chapter 98, HTSUS.

In Sigvaris, Inc. v. United States, 227 F. Supp 3d 1327, 1336 (Ct. Int'l Trade 2017), aff'd, 899 F.3d 1308 (Fed. Cir. 2018), the U.S. Court of International Trade (CIT) explained that "specially" means "to an extent greater than in other cases or towards others" and "designed" means something that is "done, performed, or made with purpose and intent often despite an appearance of being accidental, spontaneous, or natural." We must first evaluate "for whose, if anyone's, use and benefit is the article specially designed," and then, whether "those persons [are] physically handicapped []." Sigvaris, 899 F.3d at 1314. The Court of Appeals for the Federal Circuit (CAFC) clarified in Sigvaris, 899 F.3d at 1314-15 that to be "specially designed," the merchandise "must be intended for the use or benefit of a specific class of persons to an extent greater than for the use or benefit of others" and adopted the five factors used by U.S. Customs and Border Protection (CBP):

> (1) the physical properties of the article itself (i.e., whether the article is easily distinguishable by properties of the design, form, and the corresponding use specific to this unique design, from articles useful to non-handicapped persons); (2) whether any characteristics are present that create a substantial probability of use by the chronically handicapped so that the article is easily distinguishable from articles useful to the general public and any use thereof by the general public is so improbable that it would be fugitive; (3) whether articles are imported by manufacturers or distributors recognized or proven to be involved in this class or kind of articles for the handicapped; (4) whether the articles are sold in specialty stores which serve handicapped individuals; and, (5) whether the condition of the articles at the time of importation indicates that these articles are for the handicapped.

The AUVI-Q is prescribed for patients suffering from severe, potentially life-threatening allergies. However, it is questionable whether such individuals are considered chronically handicapped. Research indicates that with appropriate allergy management, including allergen avoidance, medication, and immunotherapy, individuals can live a normal life despite having allergies. Epinephrine remains the first-line treatment for anaphylaxis. It acts quickly and treats all the symptoms of anaphylaxis. In Headquarters Ruling Letter (HQ) H134535, dated September 28, 2011, CBP determined that allergies do not rise to the level of chronic physical or mental impairment that substantially limits one or more major life activities, as defined under U.S. Note 4(a), Subchapter XVII, Chapter 98, HTSUS. Furthermore, while a severe allergy may necessitate ongoing vigilance, the allergic reaction itself is an acute event. Therefore, articles designed to treat or manage the immediate, acute phase of an allergic reaction fall under the "acute or transient disability" exclusion. Based on these considerations, it is our opinion that the Electronic Prompt System is ineligible for duty-free treatment under 9817.00.96, HTSUS.

The duties cited above are current as of this ruling's issuance. Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided at https://hts.usitc.gov/.

This ruling does not address the applicability of any additional duties, taxes, fees, exactions and/or other charges, which may apply to the goods discussed herein. This includes, but is not limited to, tariffs and other duties as provided for in Subchapter III to Chapter 99, HTSUS. Thus, for example, in addition to the classification stated above, the merchandise covered by this ruling may also need to be reported with either the Chapter 99 provision under which an additional tariff applies or one of the Chapter 99 provisions covering exceptions to such tariffs.

For further information to assist with the importation process, please refer to the frequently updated Cargo Systems Messaging Service (CSMS) messages at https://www.cbp.gov/trade/automated/cargo-systems-messaging-service and Frequently Asked Questions on the Trade Remedy/IEEPA page at https://www.cbp.gov/trade/programs-administration/trade-remedies/IEEPA-FAQ.

The holding set forth above applies only to the specific factual situation and merchandise description as identified in the ruling request. This position is clearly set forth in Title 19, Code of Federal Regulations (CFR), Section 177.9(b)(1). This section states that a ruling letter is issued on the assumption that all of the information furnished in the ruling letter, whether directly, by reference, or by implication, is accurate and complete in every material respect. In the event that the facts are modified in any way, or if the goods do not conform to these facts at time of importation, you should bring this to the attention of U.S. Customs and Border Protection (CBP) and submit a request for a new ruling in accordance with 19 CFR 177.2. Additionally, we note that the material facts described in the foregoing ruling may be subject to periodic verification by CBP.

This ruling is being issued under the provisions of Part 177 of the Customs and Border Protection Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, please contact National Import Specialist Fei Chen at fei.chen@cbp.dhs.gov.

Sincerely,

(for)

Evan Conceicao
Designated Official Performing the Duties of the Division Director
National Commodity Specialist Division