THE ORTHOTIC AND PROSTHETIC ALLIANCE

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MEMORANDUM

TO: O&P Alliance Members

FROM: Peter Thomas; Annika Berlin

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RE: **Navigating Application of Tariffs on Orthotics and Prosthetics**

As tariffs on U.S. imports from many countries around the world take hold during the second Trump administration, importers of medical devices and technologies are facing heightened duties and classification scrutiny. Amid this environment, a lesser known but significant exemption remains available for the orthotics and prosthetics (O&P) sector: duty-free entry under the so-called *Nairobi Protocol*, as implemented in the Harmonized Tariff Schedule of the United States (HTSUS), specifically, subheading 9817.00.96.

This memorandum examines how U.S. Customs and Border Protection (CBP) interprets this provision in practice, especially in the context of importation of orthotic and prosthetic devices, components, parts, and accessories. Drawing on administrative rulings and case law, this memorandum outlines the key legal standards and exclusion criteria, offering insight into how stakeholders in the O&P field can better document, classify, and position their products to qualify for this exemption and avoid unnecessary tariff exposure.

Background: How the Nairobi Protocol Applies to O&P Imports

The Nairobi Protocol—formally, the Protocol to the Agreement on the Importation of Educational, Scientific and Cultural Materials (1982)—was adopted to expand the duty-free treatment of materials supporting individuals with disabilities. The U.S. implemented this commitment through Subchapter XVII, Chapter 98 of the HTSUS, which provides duty-free treatment under three subheadings:

1. 9817.00.92 for articles specially designed for the blind;
2. 9817.00.94 for the mentally "handicapped"; and,
3. 9817.00.96 for the physically "handicapped."

For the O&P field, subheading 9817.00.96 is most relevant. It provides for: "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*)." Notably, this parenthetical exclusion does not appear in the original Nairobi Protocol and reflects a narrowing of the regulatory interpretation specific to U.S. law.

In practice, 9817.00.96 functions as a secondary classification that builds on a product's primary HTSUS designation. For example, a prosthetic knee may be primarily classified under 9021.39.0000 (artificial body parts). If that device is also specially designed for individuals with

permanent disabilities, and not otherwise excluded, the importer may claim duty-free entry under 9817.00.96 as a secondary designation. It is important to note, however, that while certain primary codes such as 9021.39.0000 are often associated with products that may qualify under 9817.00.96, CBP ultimately determines eligibility on a case-by-case basis by evaluating the specific design, function, and documentation provided with each entry.

This beneficial tariff treatment is not automatic. Importers must affirmatively claim duty-free treatment at the time of entry by filing supporting documentation—most often including a completed ITA-362P form —and demonstrating that the product meets CBP's eligibility criteria.

How CBP Interprets the Standard, "Specially Designed or Adapted"

A core requirement for duty-free treatment under HTSUS 9817.00.96 is that an imported article must be "specially designed or adapted for the use or benefit of" individuals with disabilities. While this phrase is not defined in HTSUS, CBP has interpreted it through administrative rulings and case law, developing a set of practical criteria. A leading CBP ruling from 1992 laid out the core criteria used to evaluate whether an item is "specially designed or adapted" for individuals with disabilities.[1]

First, CBP examines the design intent—whether the product is physically distinct from general consumer goods and specifically engineered for use by individuals with physical or mental disabilities. It then considers the likelihood of general use: if the product is commonly used by the broader public, it may not qualify, even if it provides some benefit to people with disabilities. CBP treats the "specially designed or adapted" test as a functional inquiry, not a labeling exercise. Simply describing a product as "for prosthetic use" is insufficient if its design, materials, or utility are consistent with general-purpose items.

This distinction is especially important for prosthetic technologies that might overlap with industrial or research applications. For instance, in NY N289057, CBP approved the Taska Myoelectric Hand for duty-free treatment under 9817.00.96, determining it was a complete prosthetic device designed *solely* for use by individuals with limb loss.[2] In contrast, other prosthetic components—such as motors or robotic hands with broader research or robotics applications—may be scrutinized if their function or design is not exclusive to the disability context. In such cases, eligibility often hinges on the importer's ability to demonstrate that the article is not a general-use item but is instead specially designed for assistive use.

Similarly, in the orthotics context, CBP has found that certain ankle-foot orthoses (AFOs) met the eligibility criteria for duty-free treatment. In NY N347792, CBP reviewed five different AFO models and determined that each was designed exclusively for individuals with permanent

[1] U.S. Customs and Border Protection, HQ 556449 (May 5, 1992)
[2] U.S. Customs and Border Protection, NY N289057 (September 5, 2017)

lower-limb impairments.[3] The agency noted that the orthoses had no general-use or athletic function, and that their documentation supported their disability-specific application.

This ruling illustrates how CBP applies the "specially designed" test to orthotic devices that serve a defined assistive purpose. However, even in these cases, success often depends on how well the importer demonstrates medical design intent and user specificity. Articles that straddle multiple markets, including industrial or research use, may require additional documentation to show their primary purpose is specifically for the benefit and use of people with disabilities.

"Physically or Mentally Handicapped": A Narrow Definition That May Limit Eligibility of Certain Orthotics

Eligibility for duty-free treatment under HTSUS 9817.00.96 hinges on whether the article is intended for the use or benefit of a "blind or other physically or mentally handicapped person." As defined in U.S. Note 4(a), this includes individuals with 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." Much of this language is consistent with the definition of "disability" in the Americans with Disabilities Act of 1990, as amended.

However, U.S. Note 4(b) further narrows eligibility by excluding:

(i) articles for acute or transient disability;
(ii) spectacles, dentures, and cosmetic articles for individuals not substantially disabled;
(iii) therapeutic and diagnostic articles; and,
(iii) medicine or drugs.

One federal court decision clarified that only items used to cure a condition are considered "therapeutic," while devices that help individuals manage chronic impairments—such as prosthetics or orthotics designed for long-term use by individuals with permanent mobility impairments—may still qualify for duty-free treatment. [4] As discussed above, CBP has recognized this distinction in its treatment of certain AFOs, which were found eligible under HTSUS 9817.00.96 when intended for permanent disability support.

These limitations mirror CBP's approach in other assistive device rulings. In one set of cases, CBP approved mobility aids like walkers and wheelchairs for duty-free treatment after importers provided documentation linking them to permanent disabilities.[5][6] In contrast, one CBP decision showed that items commonly used in short-term care or by the general public may not qualify for

[3] U.S. Customs and Border Protection, NY N347792 (May 8, 2025)
[4] *Richards Medical Co. v. United States*, 910 F.2d 828 (Fed. Cir. 1990)
[5] U.S. Customs and Border Protection, NY B83927 (April 25, 1997)
[6] U.S. Customs and Border Protection, NY B89466 (October 3, 1997)

duty-free treatment—even if they also benefit individuals with disabilities. [7] A 2021 CBP decision involving aluminum walking canes sold by CVS illustrates this standard. Although the canes could have been used post-operatively and might have been considered temporary in nature, they were approved because they were designed for and primarily used by individuals with chronic mobility impairments. CBP emphasized that eligibility depends on the intended design and user population, rather than incidental use.

While prosthetic devices associated with limb loss are generally clearer candidates for duty-free treatment under HTSUS 9817.00.96, the eligibility of orthotics is often more nuanced. Orthotics such as post-operative braces or carpal tunnel supports may be viewed as general-use or therapeutic items, particularly if they are intended for short-term recovery. However, they may still qualify if the importer can demonstrate that they are designed to address a chronic or permanent impairment. By contrast, stronger candidates for duty-free treatment include custom-molded AFOs, KAFOs, or foot drop stimulators prescribed for long-term neuromuscular conditions. CBP has previously recognized certain AFOs as eligible under 9817.00.96, reinforcing that orthotics can qualify when documentation clearly supports their use for managing permanent disabilities.

A Key Exclusion: Determining Whether an O&P Item is a Complete "Article" or a "Part":

One of the most consequential limitations under HTSUS 9817.00.96 is the exclusion of "parts and accessories of braces and artificial limb prosthetics." This exclusion often affects O&P imports, where modularity is common and products are frequently shipped with multiple components.

CBP has clarified that a product which is self-contained and functionally complete may qualify as a distinct "article" rather than a disqualifying "part." [8] For example, in HQ 555704, CBP determined that prosthetic feet, hands, and joints qualified as complete articles eligible for duty-free treatment under 9817.00.96. Although these devices were often used in conjunction with one another, CBP found that each was functionally self-sufficient and not essential to the operation of the others. As such, they were not considered disqualifying parts.

Accordingly, if an orthotic or prosthetic item maintains its own identity and independent function—even when used in tandem with other components—it may still be considered an eligible article under HTSUS 9817.00.96.

This analysis becomes particularly important in cases involving kits or modular prosthetic systems. As previously discussed, the Taska Myoelectric Hand was found eligible for duty-free treatment under HTSUS 9817.00.96. In NY N289057, CBP evaluated a shipment that included the Taska Hand along with multiple accompanying items: two rechargeable batteries, two chargers, a power switch, a charger connection, a Bluetooth adapter, a spare dorsal cover, and

[7] U.S. Customs and Border Protection, HQ 556449 (May 5, 1992)
[8] U.S. Customs and Border Protection, HQ 555704 (June 24, 1991)

plastic blocks used for molding a socket.[9] Rather than analyzing each of these components in isolation, CBP applied the "set" analysis found in General Rule of Interpretation (GRI) 3(b) of the HTSUS.

Under this rule, a group of items may be considered a "set" if they are:

1. Put up together to meet a particular need or carry out a specific activity, and
2. Consist of components that collectively form a coherent functional unit.

When such a set is identified, the entire grouping is classified based on the component that imparts its essential character. In the Taska ruling, CBP determined that the prosthetic hand imparted the essential character of the set, and therefore, the entire shipment—including components that might otherwise be classified as "parts or accessories"—was considered a single article. As a result, the full prosthetic hand kit qualified for duty-free treatment under HTSUS 9817.00.96.

This distinction is significant. It demonstrates that **c**ontext and configuration matter: a prosthetic component that might be considered a non-qualifying "part" when shipped alone could potentially qualify as part of an eligible article when imported as part of a complete, functionally integrated set. CBP's analysis emphasizes both the functional purpose of the overall kit and the classification logic under the HTSUS, particularly when determining whether the kit meets the Nairobi Protocol exemption.

This outcome differs from other cases in which CBP evaluated individual prosthetic components—such as knee connectors, pylons, or brackets—and found them to be disqualifying "parts" due to their lack of standalone function.[10],[11] The Taska decision thus illustrates how a strategically structured shipment, accompanied by documentation showing its integrated design and use, can result in favorable tariff treatment even when multiple components are involved.

Tariffs Squeeze O&P Providers and Manufacturers

Unlike typical consumer markets, O&P manufacturers, suppliers, and importers may face challenges absorbing tariff costs due to fixed payment structures and limited pricing flexibility. The fragmented, third-party health care payment system in the United States limits the extent to which increased tariffs can be absorbed by the end user as reimbursement levels of many payers are set well in advance and payers are loath to simply increase reimbursement to providers or consumers based on the imposition of tariffs. This stands in stark contrast to typical commercial goods that often result in inflationary pressures, where end users can decide whether or not to purchase those goods. To make matters worse, the implementation of the tariffs in 2025 has been inconsistent and unpredictable, leading to uncertainty in the marketplace and unclear impacts on O&P access to care.

[9] U.S. Customs and Border Protection, NY N289057 (Sept. 5, 2017)
[10] U.S. Customs and Border Protection, Protest No. 3501-1-000021 (June 24, 1991)
[11] U.S. Customs and Border Protection, NY A85213 (July 25, 1996)

Final Considerations

As the O&P field continues to evolve and grow globally, understanding how CBP interprets duty-free eligibility under HTSUS 9817.00.96 remains important. While the Nairobi Protocol offers a meaningful exemption for certain assistive devices and technologies, including some orthotics and prosthetics, its implementation in the United States comes with specific limitations—particularly around definitions of disability, general-use, and the exclusion of parts for braces and prosthetics. These issues have distinct implications for O&P, where many components may be imported, and pricing is shaped by third-party reimbursement. In this context, clear documentation and evidence of disability-specific design play an important role in supporting eligibility for duty-free treatment. A flow chart illustrating the pathway for determining whether particular O&P devices may receive duty free qualification can be found here.

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