DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning

Airlift PTTD Brace

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection ("CBP") has issued a final determination concerning the country of origin of the Airlift PTTD Brace. CBP has concluded that the country of origin of the Airlift PTTD Brace is Mexico for the purpose of U.S. Government procurement.

DATES: The final determination was issued on November 23, 2018. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Joy Marie Virga, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325-1511.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on 11/23/18, CBP issued a final determination concerning Airlift PTTD Brace, which may be offered to the United States Government under an undesignated government procurement contract. The final determination, HQ H299701, was issued at the request of DJO, LLC, under procedures set forth at 19 CFR Part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 USC 2511-18). In the final determination, CBP concluded that the aircell produced in Mexico imparts the final

product with its essential character. Further, the assembly operations completed in Mexico permanently attach the various parts to each other so that they lose their individual identities and become part of the completed Airlift. Therefore, the country of origin for purposes of U.S. Government procurement of the Airlift PTTD Brace is Mexico.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: November 23, 2018.

Alice A. Kipel,
Executive Director,
Regulations and Rulings,
Office of Trade.

HQ H299701

November 23, 2018

OT:RR:CTF:VS: H299701 JMV

CATEGORY: Origin

Matthew M. Caligur
Baker & Hostetler, LLP
811 Main St., Suite 1100
Houston, TX 77002-6111

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Country of Origin of Airlift PTTD Brace

Dear Mr. Caligur,

This is in response to your request of June 11, 2018 requesting a final determination regarding the country of origin of the Airlift PTTD Brace ("Airlift") on behalf of DJO, LLC ("DJO") pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21, *et seq.*). As a domestic producer of merchandise, DJO is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d) and is entitled to request this final determination.

You requested confidential treatment for certain information contained in your submission and in the file. Pursuant to 19 C.F.R. § 177.2(b)(7), the identified information has been bracketed and will be redacted in the public version of this ruling.

FACTS:

DJO is a global provider of orthopedic devices, including a broad range of products used for rehabilitation, pain management and physical therapy. The Airlift, one of the items that DJO develops, is designed for the treatment of posterior tibial tendon dysfunction ("PTTD"), or for early signs and symptoms of the adult acquired flat foot. A sample of the finished article and photographs of the components were submitted with your request. The Airlift is essentially a brace that covers the ankle and foot. Depending on the severity of the patient's condition, the Airlift can be prescribed for use as part of a conservative treatment to stabilize the foot and ankle to help prevent further degeneration. It can also be prescribed for use post-surgically and during rehabilitation. The Airlift is produced in three sizes for both the left and right foot with varying dimensions, but all have the same structure and composition and are manufactured using the process described below. Foot support and ankle stabilization are provided by the Airlift's integrated aircell and semi-rigid shells. The aircell, located under the foot arch, is integral to preventing and rehabilitating flat foot. The aircell is adjustable using a hand bulb, which is

included with the brace. When inflated, the aircell can accommodate variances in arch shapes and heights. The semi-rigid shells are anatomically designed to the shape of the ankle for secure support and stabilization. These shells help realign the ankle and support the patient. The Airlift uses a rear entry design which allows the patient to slip his or her foot into the back of the brace. Two hook and loop straps secure the brace and can be used to adjust fit. These design elements eliminate the need for lacing, improve patient compliance and make the Airlift easier to put on than custom braces.

The Airlift is produced from the following components: a form assembly from [country A], a springloaded valve from [country B], a hand bulb from [country A], an aircell from Mexico, tubing from [country C], a pneumatic coupler from [country D], an elbow from [country D], resin polyether from [country D], colorant from [country D], foam from [country C], polyurethane laminate from [country D], and polyurethane film from [country D]. Production of the Airlift takes place at DJO's facility in Tijuana, Mexico. DJO produces the aircells in Mexico using laminate polyurethane from [country D], stuffing them with foam and sewing the sides closed. DJO places the pneumatic coupling on the fixture. DJO connects the tubing to the pneumatic coupling. DJO places the aircell on the fixture to assemble the side of pneumatic coupling in the aircell tubing. DJO then inserts the completed aircells into the wrap, ensuring that the tubing is exposed and open. DJO then places the elbow and valve into the pneumatic fixtures to create an assembly, which is also placed into the wrap and connected to the tubing. The Airlift is then packaged into a box along with the hand bulb and instructional information, which is labeled for shipping.

You state that the Airlift is classified under subheading 9021.10.00, Harmonized Tariff Schedule of the United States ("HTSUS"), which provides for "Orthopedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability; parts and accessories thereof; Orthopedic or fracture appliances, and parts and accessories thereof."

ISSUE:

What is the country of origin of the Airlift for purposes of U.S. Government Procurement?

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In determining whether the combining of parts constitutes a substantial transformation, the determinative issue for CBP is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens v. United States*, 6 C.I.T. 204 (1983), *aff'd*, 741 F.2d 1368 (Fed. Cir. 1984). Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. *See* Headquarters Ruling Letter ("HQ") H125975, dated January 19, 2011. CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis.

The Court of International Trade has also applied the "essence test" to determine whether the identity of an article is changed through assembly or processing. For example, in *Uniroyal, Inc. v. United States*, 3 C.I.T. 220, 225 (1982), *aff'd*, 702 F.2d 1022 (Fed. Cir. 1983), the court held that imported shoe uppers added to an outer sole in the United States were the "very essence of the finished shoe" and thus were not substantially transformed into a product of the United States. Further, the court noted that the attachment of the outsole to the upper was a minor manufacturing or combining process which left the identity of the upper intact.

Here, the manufacturing operations that combine the Airlift into a finished product are completed at DJO's facility in Mexico and cause the various parts to lose their individual identities. In Mexico, DJO creates the tubing used to inflate the aircell, cuts the laminate polyurethane to size and shape for the aircell, fills the aircell with foam, and sews it closed. DJO then connects the tubing into the aircell using a coupler and plastic elbow, after which the aircell is sewn into the Airlift. This processing permanently attaches the various parts to each other so that they lose their individual identities and become part of the completed Airlift.

Further, similar to the shoe upper in *Uniroyal*, the aircell imparts the essence of the brace as it is the part that provides arch support to prevent or reduce adult onset flat foot, and supports the ankle to treat PTTD. While the form assembly is imported with lateral stays that work to immobilize the ankle, it is not until the insertion of the aircell that the Airlift is suitable for treatment of these conditions. Therefore, a customer is likely to make the decision to purchase the Airlift based on the function of the aircell.

As such, we find the manufacture of the aircell in Mexico and additional processing to create a fully functioning brace results in a substantial transformation of the components such that the country of origin for government procurement purposes is Mexico.

HOLDING:

The country of origin of the Airlift for purposes of U.S. Government procurement is Mexico.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

[FR Doc. 2018-26167 Filed: 11/30/2018 8:45 am; Publication Date: 12/3/2018]