

14. Competitive pilotage;
15. Recuperative rest for pilots;
16. Legislative changes;
17. Lake Ontario/Saint Lawrence River Traffic Challenges;
18. Public comment period.

A copy of all meeting documentation will be available at <https://dco.uscg.afpims.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Marine-Transportation-Systems-CG-5PW/Office-of-Waterways-and-Ocean-Policy/Office-of-Waterways-and-Ocean-Policy-Great-Lakes-Pilotage-Div/> by September 4, 2018. Alternatively, you may contact Mr. Vincent Berg as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meeting as the Committee discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period will end following the last call for comments. Contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above, to register as a speaker.

Dated: July 26, 2018.

**Michael D. Emerson,**  
Director, Marine Transportation Systems.

[FR Doc. 2018-16365 Filed 7-30-18; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Availability of Updated Privacy Impact Assessment for the Southwest Border Pedestrian Exit Field Test

**AGENCY:** U.S. Customs and Border Protection, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** U.S. Customs and Border Protection (CBP) has made available an updated Privacy Impact Assessment (PIA) for the Southwest Border Pedestrian Exit Field Test. This updated PIA, which changes the retention period for certain biometric data gathered during the test, was published on the Department of Homeland Security (DHS) Privacy Office's website on March 5, 2018.

**FOR FURTHER INFORMATION CONTACT:** Debra Danisek, Privacy Officer, U.S. Customs and Border Protection, at [debra.danisek@cbp.dhs.gov](mailto:debra.danisek@cbp.dhs.gov) or (202) 344-1191.

**SUPPLEMENTARY INFORMATION:** U.S. Customs and Border Protection (CBP) conducted a test to collect certain biometric information at the Otay Mesa port of entry from December 2015 through June 2016 ("Southwest Border Pedestrian Exit Field Test"). This test was announced in a notice published in the **Federal Register** on November 13, 2015 ("2015 Notice").<sup>1</sup> CBP published a Privacy Impact Assessment (PIA) for this test on the Department of Homeland Security (DHS) Privacy Office's website on November 6, 2015.<sup>2</sup> The purpose of the test was to determine if collecting biometrics in conjunction with biographic data upon exit from the United States would assist CBP in matching subsequent border crossing information records with previously collected entry records. The biometrics collected provide CBP with a baseline of images collected in a live environment that can be compared with existing images. CBP stated in the 2015 Notice and in the PIA that it would retain data collected during the test for one year.

Since the conclusion of the Southwest Border Pedestrian Exit Field Test, CBP has continued to explore the best collection methods and modalities for a biometric entry-exit program. CBP has found that the data collected in the Southwest Border Pedestrian Exit Field Test continues to have value because it provides CBP with a rich source of data for ongoing analysis in its efforts to implement an effective biometric entry-exit program. CBP and its vendors are able to use this data for analysis prior to expending additional time and resources to test various systems in the field. Therefore, CBP revised its retention policy for this data and published an updated PIA on the DHS Privacy Office's website on March 5, 2018. The updated PIA provides that CBP is retaining the biometric data gathered under the Southwest Border Pedestrian Exit Field Test until April 2020. It further provides that CBP is not storing the associated biographic information.

The updated PIA is available at: <https://www.dhs.gov/publication/dhscbppia-027-southwest-border-pedestrian-exit-field-test>.

<sup>1</sup> 80 FR 70241. In the 2015 Notice, the test was referred to as the "Test to Collect Biometric Information at the Otay Mesa Port of Entry."

<sup>2</sup> This PIA is available at: <https://www.dhs.gov/publication/dhscbppia-027-southwest-border-pedestrian-exit-field-test>.

Dated: July 26, 2018.

**Debra Danisek,**

CBP Privacy Officer, Privacy and Diversity Office, Office of the Commissioner.

[FR Doc. 2018-16351 Filed 7-30-18; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determination Concerning Subdermal Needle Electrodes

**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 RhythmLink International, LLC's Subdermal Needle Electrode. Based upon the facts presented, CBP has concluded that the country of origin of the Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

**DATES:** The final determination was issued on July 13, 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 no later than August 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325-0158.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on July 13, 2018, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of RhythmLink International, LLC's Subdermal Needle Electrode, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H296072, was issued 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 U.S.C. 2511-18). In the final determination, CBP concluded that the assembly and processing in China does not result in a substantial transformation. Therefore,

the country of origin of Rhythmink International, LLC's Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination 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: July 13, 2018.

Alice A. Kipel,

*Executive Director, Regulations and Rulings,  
Office of Trade.*

HQ H296072

July 13, 2018

OT:RR:CTF:VS H296072 JK

**CATEGORY:** Origin

David S. Robinson  
Nexsen Pruet, PLLC  
4141 Parklake Avenue  
Suite 200  
Raleigh, NC 27612

**RE:** U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Subdermal Needle Electrode; Substantial Transformation

Dear Mr. Robinson:

This is in response to your correspondence of March 29, 2018, requesting a final determination on behalf of Rhythmink International, LLC ("Rhythmink"), pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq.*).

This final determination concerns the country of origin of the Subdermal Needle Electrode. We note that Rhythmink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

**FACTS:**

Rhythmink is headquartered in Columbia, North Carolina and manufactures and distributes medical devices and provides custom packaging, private labeling, custom products, and contract manufacturing to its customers.

The subject merchandise is a Subdermal Needle Electrode ("Product"), a high-tensile strength

stainless steel wire cleared by the U.S. Food & Drug Administration ("FDA") for performing both stimulating and recording electrical conductor functions. The Product serves as a physical connection between a patient and medical diagnostic equipment that records and/or elicits neurophysical biopotentials. The FDA classifies and designates the Product as a "needle electrode," defined in FDA regulations as "a device which is placed subcutaneously to stimulate or to record electrical signals." See 21 C.F.R. § 882.1350.

Rhythmink's fully assembled, packaged Product consists of the following six component parts: the needle electrode, the leadwire, a miniscule amount of solder, a heat shrink tube, a protective cover for the needle, and packaging. Rhythmink sells the Product in varying lengths and styles, and end users can customize the color of the connecting leadwire. The leadwire acts as an electrical conductor that transfers low voltage electrical signals from the needle electrode to medical diagnostic equipment. You state that the functionality of the Product is common to all lengths and is unchanged by the color of the pre-connected leadwire. You also state that other varieties of needle electrodes are available in the market that are not pre-connected to a leadwire. Such needle electrodes may connect to a leadwire without soldering by using alligator clips and other removable connectors. Other varieties of needle electrodes may utilize wireless transmission, eliminating the need for a leadwire altogether.

You state that Rhythmink conducts all of the engineering and design of the Product in the United States. The engineering and design of the Subdermal Needle Electrode include the following steps: research and development; design control; IP generation; regulatory clearances; specifications; engineering drawings; work instructions; tooling, fixtures, and equipment designs; functional verification testing; sterilization validation; packaging, sterile barrier and shelf life validation; and process validations.

Rhythmink outsources the actual manufacturing and production of the FDA-compliant needle electrodes (prior to being attached to other components) to a contract manufacturer of medical devices. The contract manufacturer manufactures the needle electrode entirely in either the United States or Japan using either U.S. or Japanese stainless steel material. You state that its production processes are largely

proprietary and that the manufacturing costs are unknown. Under the manufacturing process of the needle electrode, a stainless steel wire is cut to precise lengths, and the cut wire undergoes precise facet grinding, passivation, and electropolishing. The needle electrode is manufactured to Rhythmink's precise specifications, with three facets ground onto the front end to meet sharpness and insertion force requirements. Finally, it is packaged and shipped. The country of origin of the needle electrode is marked as either the United States or Japan, depending on the country in which it was manufactured.

The Korean-origin leadwire is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical grade PVC covering. The leadwire is available in a total of 35 color options. The Korean supplier of this wire cuts the wire, crimps a socket pin, attaches a connector to one end of the wire, and ships the wire to China.

The needle electrodes from the United States or Japan are exported to China for additional assembly and processing. The 'naked' end of the Korean leadwire is soldered to the needle electrode using Chinese-origin solder, which is a mix of tin and copper and represents a quarter of a percent of the Product's cost. You state that the soldering process takes roughly a second, substantiated by a video you provided of the process, and that six operators can professionally solder 30,000 Products in a day. The soldered Product undergoes ultrasonic cleaning and drying (spin and convention drying) in bulk. A Japanese-origin heat shrink tube, available in almost 40 different diameters, is added to protect the solder joint. A U.S.-origin protective needle cover is placed over the needle electrode to prevent accidents. Finally, the product is packaged in a Tyvek pouch and cardboard packaging of Chinese-origin and re-exported to the United States.

In the United States, the Product is subject to sterilization and a randomized sampling and testing protocol prior to sale.

You provided a catalog of Rhythmink's products, which includes the Subdermal Needle Electrode. You also provided a detailed process map depicting the various processing steps involved in the engineering, manufacture, and sale of the Product, along with information on the country in which each step occurs and the skill and technology level required for each step. In addition, you provided component specifications for the Product.

**ISSUE:**

What is the country of origin of the Subdermal Needle Electrode 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.*) (“TAA”).

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 rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. See 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States 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 transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. See *United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); *National Juice Products*

*Association v. United States*, 628 F. Supp. 978 (Ct. Int’l Trade 1986).

Courts have held that when the properties and uses of a product are predetermined by the material from which it was made, no substantial transformation occurs. For example, in *Superior Wire v. United States*, 669 F. Supp. 472 (Ct. Int’l Trade 1987), *aff’d*, 867 F.2d 1409 (Fed. Cir. 1989), wire rod in coils was shipped to Canada where it was drawn into wire. The tensile strength of the final product was increased by approximately 30 to 40 percent as the rod was reduced in cross-sectional area by about 30 percent and was elongated. The court determined that the drawing operation did not result in a substantial transformation, pointing out that the properties of the wire rod and its uses were determined by the chemical content of the rod and the cooling processes used in its manufacture, and that the wire rod dictated the final form of the finished wire.

For purposes of this ruling, we assume that the country of origin of the stainless steel wire used to manufacture the needle electrode is the United States or Japan. You assert that the assembly and processing that occurs in China, a non-designated country, does not substantially transform the U.S. or Japanese-origin needle electrode, claimed to be the essential character of the Product, into a new and different article of commerce.

In HQ 555774, dated December 10, 1990, Customs, a predecessor of CBP, ruled that Japanese-origin wire cut to varying length and electrical connectors crimped onto the ends of the wire in the United States did not constitute substantial transformation. Customs found that the essential character and use of the wire before and after the processing was the same, *i.e.*, to conduct electrical current.

In HQ H248851, dated July 8, 2014, CBP held that an Israeli-origin CO2 tube was not substantially transformed in China when cut to length and attached to four other components from Israel and China. CBP found that the CO2 tube performed the essential function of the finished product, which was the delivery of breath for monitoring the CO2 level in a patient’s breath. By way of the assembly process in China, the CO2 tube was attached to other components that facilitated its function and did not lose its individual identity in the process.

Like the operations described in HQ 555774 and HQ H248851, the assembly and processing that occur in China are simple and minor processes that leave the identity of the needle electrode

intact. The soldering of the leadwire to the needle electrode occurs in roughly one second. The remaining processing of the Product, consisting of cleaning and drying, adding a heat shrink and protective cover, and packaging, are likewise simple and minor operations involving highly repetitive, low-skill functions.

As in *Superior Wire*, the properties and uses of the Product are predetermined by the qualities of the needle electrode itself, which do not change as a result of the Chinese assembly and processing operations. The Product’s main function is to penetrate the skin or other membrane to allow medical diagnostic equipment to record or stimulate neurophysical biopotentials. While the presence of a pre-connected leadwire does provide convenience for the end user, by eliminating the need to use removable connectors for attaching a leadwire, the needle electrode is nonetheless capable of performing its main function without a pre-connected leadwire. Prior to any Chinese assembly or processing, the needle electrode already meets the definition of the FDA regulated “needle electrode.” As in HQ H248851, the attachment of the leadwire and other components to the needle electrode may facilitate its function, but the needle electrode does not lose its individual identity in the process. As a result, we find that the U.S. or Japanese-origin needle electrode, rather than the Korean-origin leadwire, determines the essential character of the Product.

We find that the name, character, and use of the needle electrode remain unchanged after the attachment of the leadwire and other components. Accordingly, we find that the needle electrode is not substantially transformed as a result of the Chinese assembly and processing operations.

**HOLDING:**

The country of origin of the Subdermal Needle Electrode for U.S. Government procurement purposes is the United States or Japan, depending on the country of origin of the needle electrode.

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 after 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 and Rulings  
Office of Trade

[FR Doc. 2018-16281 Filed 7-30-18; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2018-0003]

### Privacy Act of 1974; System of Records

**AGENCY:** Department of Homeland Security.

**ACTION:** Notice of a new system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to consolidate two legacy systems of record, Department of Homeland Security/U.S. Citizenship and Immigration Services-002 Background Check Service and Department of Homeland Security/U.S. Citizenship and Immigration Services-003 Biometric Storage System into the new DHS system of records titled, "Department of Homeland Security/U.S. Citizenship and Immigration Services-018 Immigration Biometric and Background Check System of Records." This system of records notice (SORN) allows the DHS U.S. Citizenship and Immigration Services (USCIS) to collect and maintain biographic, biometric, and background check records on applicants, petitioners, sponsors, beneficiaries, or other individuals in connection with a benefit request. USCIS uses biometric and associated biographic information to verify identity, conduct criminal and national security background checks against internal and external government systems, and to support domestic and foreign data sharing agreements. The categories of individuals, categories of records, and the routine uses of these legacy systems of records notices have been consolidated and updated to better reflect the Department's biometric and biographic criminal background checks; identity enrollment, verification, and resolution; document production record systems; and data sharing efforts.

Additionally, DHS is issuing a Notice of Proposed Rulemaking (NPRM) to exempt this system of records from certain provisions of the Privacy Act, elsewhere in the **Federal Register**. This

new system will be included in DHS's inventory of record systems.

**DATES:** Submit comments on or before August 30, 2018. This system will be effective upon publication. Routine uses will become effective August 30, 2018.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2018-0003 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-343-4010.

- *Mail:* Philip S. Kaplan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

*Instructions:* All submissions received must include the agency name and docket number DHS-2018-0003 for this notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions, please contact: Donald K. Hawkins, (202) 272-8030, [USCIS.PrivacyCompliance@uscis.dhs.gov](mailto:USCIS.PrivacyCompliance@uscis.dhs.gov), Privacy Officer, U.S. Citizenship and Immigration Services, 20 Massachusetts Avenue NW, Washington, DC 20529. For privacy questions, please contact: Philip S. Kaplan, (202) 343-1717, [Privacy@hq.dhs.gov](mailto:Privacy@hq.dhs.gov), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

DHS USCIS has relied on two preexisting DHS/USCIS Privacy Act SORNs for the maintenance of USCIS biometric and background check records: "DHS/USCIS 002 Background Check Service," 72 FR 31082 (June 5, 2007), and "DHS/USCIS-003 Biometric Storage System," 72 FR 17172 (April 6, 2007). Such records will be covered by one new system of records named "DHS/USCIS-018 Immigration Biometric and Background Check (IBBC) System of Records." USCIS processes and adjudicates most immigration benefit requests and other immigration request forms (e.g., applications and petitions) for DHS. This new system of records notice consolidates and covers all of USCIS's biometric and associated biographic information it collects pursuant to that mission. The purpose of this system is to verify identity and conduct criminal and national security

background checks in order to establish an individual's eligibility for an immigration benefit or other request, and support domestic and international data sharing efforts. USCIS determines eligibility by capturing biometric and associated biographic data from benefit requestors, beneficiaries, and other categories of individuals to facilitate three key operational functions: (1) Verify an individual's identity; (2) conduct criminal and national security background checks; and (3) produce benefit cards and documents as a proof of benefit.

Most individuals who file benefit requests for themselves or on the behalf of others (i.e., petitioner, applicants, beneficiaries, and requestors) are subject to background, identity, and security checks to ensure eligibility for the requested benefit. Other individuals in connection with immigration benefit requests or other requests (i.e., household members, sponsors) may also be subject to certain background, identity, and security checks. The biometric collection process begins with the capture of biometric data at an authorized biometric capture site, including USCIS offices, Application Support Centers, or U.S. consular offices and military installations abroad. USCIS requires applicants, petitioners, sponsors, beneficiaries, or other individuals in connection of a benefit request to submit their biometrics along with associated biographic information to USCIS for background, identity, and security checks. The types of background checks USCIS conducts vary by the benefit or request type. Standard background checks may include, but are not limited to:

##### *Biometric based checks:*

- Federal Bureau of Investigation (FBI) Next Generation Identification (NGI) Biometric Check;
  - DHS Office of Biometric and Identity Management (OBIM) Automated Biometric Identification System (IDENT) Biometric Check;
  - Department of Defense (DoD) Automated Biometric Identification System (ABIS) Biometric Check;
- Biographic name-based checks:*
- FBI Central Records System (CRS) and Universal Index (UNI) Name Check;
  - U.S. Customs and Border Protection (CBP) TECS Name Checks;
  - Department of State (DOS) Consular Lookout and Support System (CLASS); and
  - DOS Security Advisory Opinion (SAO).

USCIS may also perform interagency checks with intelligence community partners for certain benefits. The results of these checks are used to inform