DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Ultrasound Systems

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 certain ultrasound systems. Based upon the facts presented, CBP has concluded in the final determination that the U.S. is the country of origin of the ultrasound systems for purposes of U.S. government procurement.

DATE: The final determination was issued on April 3, 2013. A copy of the final determination is attached. Any party-at-interest, as defined in 19 C.F.R. § 177.22(d), may seek judicial review of this final determination on or before [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Elif Eroglu, Valuation and Special Programs Branch: (202) 325-0277.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on April 3, 2013 , pursuant to subpart B of part 177, Customs Regulations (19 C.F.R. part 177, subpart B), CBP issued a final determination concerning the country of origin of the Siemens Medical S2000 and Antares ultrasound systems which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, Headquarters Ruling Letter ("HQ") H219597, was issued at the request of Siemens Medical Solutions USA under procedures set forth at 19 C.F.R. 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 has concluded that, based upon the facts presented, the assembly of the S2000 and Antares ultrasound systems in the U.S., from parts made in Japan, Korea, Italy, China, and the U.S., constitutes a substantial transformation, such that the U.S. is the country of origin of the finished articles for purposes of U.S. government procurement.

Section 177.29, Customs Regulations (19 C.F.R. § 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 C.F.R. § 177.30), provides that any party-at-interest, as defined in 19 C.F.R. § 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

DATED: April 3, 2013

Sandra L. Bell

Executive Director

Regulations and Rulings

Office of International Trade

Attachment

HQ H219597

April 3, 2013

OT:RR:CTF:VS H219597 EE

CATEGORY: Marking

Alan W. H. Gourley
Crowell & Moring LLP
1001 Pennsylvania Ave., NW
Washington, D.C. 20004

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

Dear Mr. Gourley:

This is in response to your correspondence of January 30, 2012 and additional information you submitted on May 22, 2012, July 23, 2012, August 29, 2012, and September 4, 2012, requesting a final determination on behalf of Siemens Medical Solutions USA, Inc. ("Siemens Medical"), pursuant to subpart B of part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting between counsel and this office occurred on November 13, 2012 to allow counsel the opportunity to discuss the case and present further arguments. Counsel submitted an additional supplemental submission on November 16, 2012. Under the pertinent regulations, which implement Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq*.), 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 purpose of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of the Siemens Medical S2000 and Antares ultrasound systems. We note that Siemens Medical 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:

The merchandise at issue are two Siemens Medical ultrasound units, known as the S2000 and Antares ultrasound systems, engineered, designed, and subject to final assembly in the U.S. from U.S. and foreign components. The S2000 and Antares ultrasound systems are diagnostic imaging systems that transmit sound waves and then receive and process the echoes of those waves to create a visual representation of a patient's tissues and organs. You state these systems comprise three core elements: (1) the transducers that send and receive the acoustic signals from the patient; (2) the electronics module that processes signals and "beamform" the data to convert it into a form that can be used by Siemens' proprietary application software; and (3) the application software that manipulates and displays the patient image data to allow for diagnostic and prescriptive use by healthcare professionals.

One of the most critical elements required for the manufacture of a functional ultrasound system is the transducer which is the handset that is passed over the surface of the patient's body, where it produces high-frequency sound waves that penetrate the area of the body being scanned. The transducer focuses the sound-wave beam of pulses into specific dimensions as well as scans the beam over the region of interest in the patient's anatomy. The transducer then receives the "echo" of these sound waves as they rebound from the patient's internal organs and tissue, and transmits this returned data (as electrical impulses) to the electronics module. The quality of the beam and return echo define the quality of the signal and resulting image which is of key significance to the diagnostician employing the ultrasound. The typical customer-ordered S2000 or Antares ultrasound systems will have three or more transducers that allow for application-specific usage. The transducers are manufactured in Korea.

The electrical signals from the transducer are processed by the electronics module and, once converted to usable digital data, manipulated by the application software and then displayed on the machine's monitor for the clinical user. The proprietary software is run on what are essentially commoditized computer hardware components.

The application software is stated to be the key element that enables the electronics module to "translate" the data received from the transducer into an image to be displayed on the monitor. The software performs a variety of functions including standard work flow items such as archiving and displaying patient data as well as image data manipulation/transformation, custom display, and analytics/calculations. Depending on the specific customer's intended end-use (*e.g.,* cardio or prenatal) and requirements, different aspects of the software may be activated/enabled through the use of licensing keys.

Manufacturing Process

Electronics Module Assembly:

You state that the manufacturing of the electronics module in China involves: (1) the incorporation and testing of the Chinese-origin circuit boards (printed wiring assemblies) to specification; and (2) the incorporation of Chinese-origin real-time manager assembly, which includes a commercial computer motherboard, CPU, hard drive, and video card. These assembly operations also require the installation of Chinese-origin subcomponents and sub-assemblies including:

- A "backplane" which is a circuit board that connects the various system boards;
- A "cardcage" which is a mechanical structure to which the backplane is bolted;
- A "continuous beamformer" used for Doppler imaging to depict both visual images and audio interpretation of blood flow;
- A power supply system (including a U.S.-origin transformer, Japanese-origin power supplies for both the analog and digital portions of the system, and the alternating current tray and cable that will connect to the external power receptacle); and
- A trolley frame assembly, which is the structure that houses the CPU and that ultimately will house the other components added after importation into the U.S. (i.e., the monitor, the control panel, connecting cables, transducers, etc.).

Following assembly of the electronics module, the test version of the Siemens Medical's operating system software, which is designed, engineered, and written in the U.S., is uploaded onto the real-time manager assembly hard drive to test the hardware to correct any manufacturing defects. The testing involves the use of a temporary licensing schema (via the use of a USB license key tool) to temporarily enable various application features. Once the testing is completed and the USB thumb drive is removed, the software is no longer enabled. You state that the condition of the system when it leaves Shanghai is a tested, but incomplete electronics module. You state that even with the application of power, the addition of a control panel, monitor, and transducers, the electronics module, in its form as exported from China, could not be used as a diagnostics ultrasound machine.

Ultrasound System Integration and Testing:

After importation, the partially completed electronics module initially arrives to the facility of a Siemens Medical contract manufacturer in San Jose, CA for completion of the electronics module. This includes the installation of the Italian-origin monitor, the

U.S.-origin control panel, and the U.S.-origin outer covers that cover the electronics, the alternating current tray, and the transformer.

In addition, depending on the specific customer order at issue, the assembly may also include installation of the "Physio Module" (a component that provides the system with an interface to patient respiration and electrocardiogram (ECG) data, whereby that data can be overlaid on the ultrasound image such that a video clip of the imaging data will include ECG and respiration data in real time) and a digital video recorder assembly.

Once the assembly is completed, the following series of tests and system adjustments are performed:

- Electrical safety testing of the components.
- Calibration of the Italian-origin display monitor using a specific ultrasound imaging procedure.
- Diagnostic and imaging tests using Korean-origin "slave" transducers to ensure proper functioning of the control panel and monitor.
- 24 hours of reliability testing for any latent failures. This involves a series of power-on and power-off operations, customer use simulations, stress testing of the real-time manager assembly, automated software tests, and tests of numerous standby operations.

At the conclusion of the reliability testing, the system is checked for cosmetic acceptance, which involves a physical review of the product against certain customer criteria. The system is then packaged and shipped to Siemens Medical's Buffalo Grove, Illinois location for final assembly, configuration and testing.

Final Assembly, Configuration, and Testing:

Upon arrival at Siemen's Medical's Buffalo Grove facility, the system is "whitewashed", where the test version of the software is wiped from the system in its entirety. Next, the most current version of the operating system software, which is designed, developed, and written in the U.S., is uploaded to each unit using DVDs. The application software is enabled by loading the permanent licensing keys into the system using a web-based tool that interfaces with Siemen's enterprise resource planning system (SAP). You state that every feature and system type has a unique license key. The web-based tool identifies the features and system type as shown in the customer's order in the SAP and creates the corresponding license key file on a DVD or USB drive. That file, in turn, is uploaded to the unit and enables only the purchased features in the systems software. Next, the equipment is adjusted and configured to meet customer requirements for line voltage (including addition of the appropriate power cord), language (control panel overlay and system software settings), and documentation devices (printer etc.). An electrical safety test is then performed on the system's final configuration. The final test process is the execution of the Customer Relevant Simulation Testing, which is a high-level imaging process that uses the customer

ordered Korean-origin transducers and capitalized transducers to fully test the functionality of the complete ultrasound system (including customized applications, transducers, system, and peripherals). You state that this test requires a highly trained skilled diagnostician as it is intended to replicate the customer's intended user environment.

The S2000 ultrasound system is comprised of approximately 19 subassemblies and additional components. It takes approximately 23-24 hours to produce the finished S2000 ultrasound system of which 13-14 hours takes place in the U.S. The Antares ultrasound system is comprised of 17 subassemblies and additional components. It takes approximately 24-25 hours to produce the finished Antares ultrasound system of which 14-15 hours takes place in the U.S.

You submitted the costed bill of materials for the S2000 and Antares ultrasound systems. You also submitted a copy of the product brochures for the S2000 and Antares systems. Additionally, you provided pictures of various transducers, the electronics components, the partially completed electronics module, the list of printed wire assemblies and functions, and the manufacturing process flow chart.

ISSUE:

What is the country of origin of the S2000 and Antares ultrasound systems for the purpose of U.S. government procurement?

LAW AND ANALYSIS:

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.*), 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.

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 the 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.

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process will be considered when determining whether a substantial transformation has occurred. No one factor is determinative.

In *Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982), the court observed that the substantial transformation issue is a "mixed question of technology and customs law."

In *Data General v. United States*, 4 Ct. Int'l Trade 182 (1982), the court determined that for purposes of determining eligibility under item 807.00, Tariff Schedules of the United States (predecessor to subheading 9802.00.80, Harmonized Tariff Schedule of the United States), the programming of a foreign PROM (Programmable Read-Only Memory chip) in the United States substantially transformed the PROM into a U.S. article. In programming the imported PROMs, the U.S. engineers systematically caused various distinct electronic interconnections to be formed within each integrated circuit. The programming bestowed upon each circuit its electronic function, that is, its "memory" which could be retrieved. A distinct physical change was effected in the PROM by the opening or closing of the fuses, depending on the method of programming. This physical alteration, not visible to the naked eye, could be discerned by electronic testing of the PROM. The court noted that the programs were designed by a U.S. project engineer with many years of experience in "designing and building hardware." While replicating the program pattern from a "master" PROM may be a quick one-step process, the development of the pattern and the production of the "master" PROM required much time and expertise. The court noted that it was

undisputed that programming altered the character of a PROM. The essence of the article, its interconnections or stored memory, was established by programming. The court concluded that altering the non-functioning circuitry comprising a PROM through technological expertise in order to produce a functioning read only memory device, possessing a desired distinctive circuit pattern, was no less a "substantial transformation" than the manual interconnection of transistors, resistors and diodes upon a circuit board creating a similar pattern.

HQ H203555, dated April 23, 2012, concerned the country of origin of certain oscilloscopes. CBP considered five manufacturing scenarios. In the various scenarios, the motherboard and the power controller of either Malaysian or Singaporean origin were assembled in Singapore with subassemblies of Singaporean origin into oscilloscopes. CBP found that under the various scenarios, there were three countries under consideration where programming and/or assembly operations took place, the last of which was Singapore. CBP noted that no one country's operations dominated the manufacturing operations of the oscilloscopes. As a result, while the boards assembled in Malaysia were important to the function of the oscilloscopes and the U.S. firmware and software were used to program the oscilloscopes in Singapore, the final programming and assembly of the oscilloscopes was in Singapore and hence represented the last substantial transformation. Therefore, CBP found that the country of origin of the oscilloscopes was Singapore.

HQ H170315, dated July 28, 2011, concerned the country of origin of satellite telephones. CBP was asked to consider six scenarios involving the manufacture of PCBs in one country and the programming of the PCBs with second country software either in the first country or in a third country where the phones were assembled. In the third scenario, the application and transceiver boards for satellite phones were assembled in Malaysia and programmed with U.K.-origin software in Singapore, where the phones were also assembled. CBP found that no one country's operations dominated the manufacturing operations of the phones and that the last substantial transformation occurred in Singapore. *See also* HQ H014068, dated October 9, 2007 (CBP determined that a cellular phone designed in Sweden, assembled in either China or Malaysia and shipped to Sweden, where it was loaded with software that enabled it to test equipment on wireless networks, was a product of Sweden. Once the software was installed on the phones in Sweden, they became devices with a new name, character and use, that is, network testing equipment. As a result of the programming operations performed in Sweden, CBP found that the country of origin of the network testing equipment was Sweden).

In this case, substantial manufacturing operations are performed in China, the U.S., Korea, and Italy. The electronics module, which is partially assembled in China, is imported into the U.S., where it is assembled with other core components, including the Korean-origin transducers that send and receive the acoustic signals, the Italian-origin monitor that permits display of images, and the U.S.-origin control panel that serves as the user interface. The completely assembled ultrasound systems are then uploaded with U.S. designed, developed, and written operating system software and application

software. You state that the software is necessary for the ultrasound systems to perform their intended function of providing diagnostic information (an observable image with related data). As previously noted, it takes approximately 23-24 hours to produce the finished S2000 ultrasound system of which 13-14 hours takes place in the U.S. It takes approximately 24-25 hours to produce the finished Antares ultrasound system of which 14-15 hours takes place in the U.S. You claim that the assembly, integration, and testing in the U.S. is conducted by specialized technicians. You also state that all of the research & development, product engineering and design investment occur in the U.S. Based on the totality of the circumstances, we find that the last substantial transformation occurs in the U.S., the location where the final assembly and installation of the operating system software and application software occurs. Prior to the assembly and programming in the U.S., the products are unable to carry out the functions of ultrasound systems. However, the assembly and programming in the U.S. creates a new product that is capable of providing diagnostic information. Consequently, we find that the country of origin of the ultrasound systems is the U.S.

HOLDING:

The imported components that are used to manufacture the S2000 and Antares ultrasound systems are substantially transformed as a result of the assembly and software installation operations performed in the U.S. Therefore, we find that the country of origin of the S2000 and Antares ultrasound systems for government procurement purposes is the U.S.

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,

Sandra L. Bell
Executive Director
Regulations and Rulings
Office of International Trade

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