



## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determination Concerning a Digital Radiography System

**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 a digital radiography system, (also commonly referred to as an x-ray system), known as the Carestream DRX-Ascend Digital Radiography system. Based upon the facts presented for purposes of U.S. Government procurement, CBP has concluded that the United States is the country of origin of the fully assembled and installed DRX-Ascend Digital Radiography system.

**DATES:** The final determination was issued on June 30, 2017. 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 within [insert 30 days from date of publication in the Federal Register].

**FOR FURTHER INFORMATION CONTACT:** Robert Dinerstein, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325-0132.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on June 30, 2017 pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 C.F.R. Part 177, subpart B), CBP issued a final determination concerning the country of origin of a digital radiography system known as the Carestream DRX-Ascend Digital

Radiography system, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H283088, was issued 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). The major components of the DRX-Ascend Digital Radiography system include a Chinese-origin high-voltage generator, a U.S.-origin wireless DRX detector, a Chinese-origin elevating float-top table, a Chinese-origin tubestand, a Chinese-origin wall stand, and either a U.S. or a Japanese-origin x-ray tube. These components are combined with software that is largely developed in the United States. In the final determination, CBP concluded that the components are substantially transformed in the United States when the fully functioning digital radiography system is completely assembled and installed at an on-site location. Thus, the fully assembled digital radiography system becomes a product of the United States. Therefore, for purposes of U.S. Government procurement, the United States is the country of origin of the installed and assembled Carestream DRX-Ascend Digital Radiography system.

Section 177.29, CBP Regulations (19 C.F.R. § 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 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: June 30, 2017

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

**HQ H283088**

**OT:RR:CTF:VS H283088 RSD**

**CATEGORY: Origin**

Gunjan R. Talati, Esq.  
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Washington, D.C. 20005-2018

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

Dear Mr. Talati:

This is in response to your letter of January 11, 2017, forwarded to the National Commodity Specialist Division on behalf of Carestream Health, Inc. (Carestream), requesting a final determination concerning the country of origin of a Digital Radiography System, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. § 177.21, *et seq.*). The National Commodity Specialist Division transmitted your request to the Office of Trade, Regulations and Rulings Headquarters for a response. 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 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.

This final determination concerns the country of origin of a digital radiography system, which will be assembled on-site. As a U.S. importer, Carestream 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 product at issue is a digital radiography system known as the DRX-Ascend Digital system that is assembled in the United States from U.S. and foreign origin components. According to the information that you have provided, the DRX-Ascend Digital system is a digital radiography system (also commonly known as an x-ray system) engineered, designed, and assembled (final assembly) in the United States from seven major U.S. and foreign-origin components. The seven components are (1) a diagnostic x-ray high voltage generator; (2) wireless DRX Detector; (3) an x-ray tube; (4) a tubestand; (5) an elevating float-top table; (6) a wall stand; and, (7) Carestream Health software.

The diagnostic x-ray high-voltage generator supplies and controls the electrical energy applied to a diagnostic x-ray tube for medical/veterinary radiographic examinations. The initial manufacturing of the generator occurs in China, where Chinese components of the generator are provided by Chinese suppliers. The generator goes through two hours of processing in China to produce an unfinished generator. Carestream imports the unfinished generators into the United States. When it is imported, the generator does not contain the necessary printed circuit boards, and it also needs to be programmed. The printed circuit boards are stated to be manufactured in the United States and will be programmed using software written by a company called Quantum Manufacturing located in New York. Adding the boards to the generator and programming in the United States take roughly one hour of manufacturing time. The generator then undergoes extensive testing (approximately 6.5 hours) in the United States. You maintain that this testing is critical to the generator manufacturing process of the DRX-Ascend Digital system and must be completed before Carestream delivers the system to the customer.

The wireless DRX Detector, produced in the United States, utilizes Directview software and facilitates diagnostic exams by capturing the x-ray images and wirelessly transmitting them to a capture console that allows for immediate viewing at the capture console and manipulation. The chief benefit of instant image access is that it can reduce exam time and recall, and improves patient satisfaction. The detector is integrated into the DRX-Ascend Digital system by both hardware and software and you indicate that the detectors are made in the United States by Carestream Health or an external supplier.

The x-ray tube converts power into x-rays that ultimately produce the image required for making a diagnosis. Carestream uses two suppliers to obtain the x-ray tubes, either from Japan or the United States.

Another component of the DRX-Ascend Digital system is an elevating float-top table made in China. The tubestand component of the table is assembled in the United States and holds three different parts. One of these parts is the x-ray tube, and the other two parts are an operator panel and the collimator, all of Chinese origin. Some of the tubestands have an overhead tube crane from Germany. These parts are installed on-site at the customer's location in the United States by a U.S. service provider. The time for manufacturing the basic stand is approximately six hours in China. The tubestand is then brought into the United States for final assembly. The final assembly takes about two hours. The DRX-Ascend Digital system can include a wall stand. The wall stand is fully assembled in China.

The final element of the DRX-Ascend Digital system is the Carestream Directview software, which is initially programmed and developed in the United States. While the software build is currently performed in China, substantial portions of the software are still developed in the United States. According to your submission, two percent of the Directview software involves research and 100 percent of that research was performed in the United States. The development/writing of the software specifications and architecture involve 15 percent of the project, with 90 percent of this work being done in the United States and 10 percent completed in China. Programming of the source code involved 40 percent of the creation of the software project, with 80 percent occurring in the United States and the remaining 20 percent done in China. Two percent of the product concerns the software build, with 100 percent of the software build done in China. Testing and validation involved 40 percent of the project of the software with 50 percent of this portion of the software done in United States and 50 percent done in China. The final one percent was preparing the software/burning media for distribution, with 50 percent done in United States and 50 percent done in China. The Directview software is installed onto an HP 5810 computer in China, and that computer with the loaded software is brought to the United States. This software has two primary functions: (1) allowing the operator to select the type of medical exam and selecting the generator and x-ray tube exposure settings (the computer then coordinates the timing between the detector and firing of the x-rays), and (2) the computer and software receive the image from the detector, process the image, and deliver the finished image.

The final assembly, configuration and testing of the DRX-Ascend Digital system take place in the United States at Carestream's facilities or at its customers' sites. You describe the assembly process as consisting of nine steps before the DRX-Ascend Digital system can become a functioning x-ray system. You have provided a copy of an installation guide, which sets forth the step-by-step process of installing the DRX-Ascend Digital System at a customer's site. The installation guide consists of over 80 pages of detailed instructions for the installation technicians, describing how the DRX-Ascend Digital System is assembled and installed at an on-site location. The ancillary parts for the system from China, including the table, the wall stand, a tubestand and the computer with the Directview software loaded onto it are assembled together in the United States. The x-ray tube and generator are calibrated together in the United

States so that they can work together to produce an image. The generator tube-calibration process works by having the generator send a signal to the tube, and the tube responds and fires x-rays. The tube is then removed and reinserted into the x-ray system. The generator and the detector use the same calibration process. Carestream integrates the digital detector. The x-ray tube, generator, and detector are added to the Chinese ancillary parts. The DRX-Ascend Digital system is then shipped to and installed at a customer's site. When the system is installed at the customer's site, all the components are connected and powered, at which time the DRX-Ascend Digital system becomes a functioning radiography x-ray system.

You indicate that individuals responsible for the on-site installation are either Carestream employees or Carestream dealer employees. All individuals responsible for installation receive formal classroom training through multiple courses at Carestream. The first course is a four-day-long class on x-ray fundamentals. The second course is a five-day class on Carestream's DRX systems. The third course is a certification course that is also four days and teaches the students to become proficient in installing, calibrating, and repairing the DRX-Ascend Digital system.

Some of the specialized tools and equipment that the x-ray installers use in performing the installation include a digital volt meter, x-ray measurement meter, mAS meter, dose meter, high voltage insulating kit, and ratchet hoists. You further state that it typically takes four to five days to install the system at a customer site depending on site readiness, but the system is designed for installation in four days.

#### **ISSUE:**

What is the country of origin of the DRX-Ascend Digital x-ray system for purposes 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."

Headquarters Ruling (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; hence,

Singapore imparted the last substantial transformation, and 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: 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 HQ H219597, dated April 3, 2013, ultrasound systems were engineered, designed and subject to final assembly in the United States from U.S. and foreign components. CBP noted that substantial manufacturing operations were performed in China, the United States, Korea, and Italy. The electronics module, which was partially assembled in China, was imported into the United States, where it was assembled with other core components, including Korean-origin transducers that sent and received acoustic signals, an Italian-origin monitor that displayed images, and a U.S.-origin control panel that served as the user interface. The completely assembled ultrasound systems were then uploaded with U.S. designed, developed, and written operating system software and application software. The information provided indicated that the software was necessary for the ultrasound systems to perform their intended function of providing diagnostic information (an observable image with related data). It took approximately 23-24 hours to produce the finished S2000 ultrasound system of which 13-14 hours took place in the United States. Approximately 24-25 hours of time were expended to produce the finished Antares ultrasound system of which 14-15 hours took place in the United States. In addition, the assembly, integration, and testing in the United States was conducted by specialized technicians. All of the research and development, product engineering and design investment occurred in the United States. Based on the totality of the circumstances, CBP found that the last substantial transformation occurred in the United States, the location where the final assembly and installation of the operating system software and application software occurred. Prior to the assembly and programming in the United States, the products were unable to carry out the functions of the ultrasound systems. However, the assembly and programming in the United States created a new product that was capable of providing diagnostic information. Consequently, CBP found that the country of origin of the ultrasound systems was the United States.

Similarly, in this case, it is noted that there is a significant amount of U.S. assembly involved in producing the complete x-ray system on-site. We note that Carestream has a detailed step-by-step instruction booklet for the installation technicians on how to properly install and assemble the x-ray system. We note that there are a series of complicated steps and operations that must be carefully followed in assembling the components of the x-ray system in order to make sure that the finished installed x-ray system works properly. In addition, we recognize that major safety issues could arise for future patients and operators, if the assembly and installation of an x-ray system is not done correctly. As such, the assembly requires the precise fitting, assembly, and calibration of the various components together in making the finished x-ray system. As previously noted, Carestream's technicians must undergo a series of intensive classroom training through multiple courses in order to obtain the necessary skills to be able to install and assemble the x-ray system. These technicians also use some highly specialized and sophisticated tools in completing the assembly and installation of an x-ray system.

While the x-ray system is comprised of various components mostly from China and the United States (in some cases a Japanese x-tube will be used), there is no one single component, which dominates and retains its own identity after the system is put together. We also note that while one of the more significant components, the system's high voltage generator, is of Chinese origin, it is unfinished when imported into the United States. The boards, which make the generator operational, are installed and programmed in the United States, and the finished generator undergoes significant testing in the United States before Carestream delivers the system to the customer in the United States.

Furthermore, while simply installing the U.S. developed software onto the x-ray system alone would not be sufficient to result in a substantial transformation of the foreign made components, we note that according to the information submitted, the U. S. origin software does play an integral role in the final product's proper functioning. More significantly, because a substantial assembly operation occurs in installing the x-ray system at the on-site location, more than just loading of software is involved in making the finished x-ray systems in the United States. Until all of the components are put together into the completed system, it will not have the character of an x-ray system, and the individual components cannot carry out the functions of an x-ray system of producing radiographic images suitable for making a diagnosis. We also find it highly significant that the information provided indicates the assembly and installation of the x-ray system require a significant amount of time, in that it usually takes about 4 to 5 days on-site to complete. As in HQ H219597, after the assembly and programming of the U.S. and foreign made components are completed in the United States, the foreign made components all lose their individual identities and connected together will create a distinct new product, an x-ray system, which is capable of providing radiographic images for diagnostic purposes. Consequently, we find that a product with a new name, character, and use is produced by the operations performed in the United States to

make the x-ray system, and thus the country of origin of the DRX-Ascend Digital x-ray system is the United States.

**HOLDING:**

Based on the information presented, the imported components that are used in the manufacture of the DRX-Ascend Digital x-ray system are substantially transformed as a result of the assembly operations and the software installation performed at an on-site location in the United States. Therefore, the country of origin of the DRX-Ascend Digital Radiography x-ray system for government procurement purposes is the United States.

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 and Rulings  
Office of Trade

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