DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determinations Concerning Country of Origin of The Hub and Mobile Platforms, and The AMC Home Tele-Health System

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

ACTION: Notice of final determinations.

SUMMARY: This document provides notice that U.S. Customs and Border Protection ("CBP") has issued two final determinations concerning the country of origin of tablet computers and smart phones known as the Hub and Mobile Platforms, and CareConsole Hub and Mobile Hub. CBP has concluded in the final determinations that for purposes of U.S. Government procurement the installation of proprietary software on tablet computers or smart phones does not substantially transform the imported tablet computers or smart phones.

DATES: The final determinations were issued on February 21, 2018. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 C.F.R. § 177.22(d), may seek judicial review of these final determinations 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 February 21, 2018, CBP issued two final determinations concerning the country of origin of tablet computers, smart phones, and systems, which may be offered to the United States

Government under an undesignated government procurement contract. These final determinations, HQ H284834 and HQ H284617, were issued at the request of 1Vision, LLC and Care Innovations, LLC, respectively, 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 determinations, CBP was asked to consider whether disabling the general applications of a tablet computer or smart phone and loading specialized software onto the device, enabling a patient to provide medical information to the VA, constituted a substantial transformation. In one final determination, CBP was further asked if the integration of the altered tablets and smartphones into a larger telehealth system constituted a substantial transformation. In the final determinations, CBP concluded that these activities do not constitute a substantial transformation and the origin of the tablet computers, smart phones, and systems remains the original country of manufacturing.

Section 177.29, CBP 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: February 21, 2018.

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

HQ H284834

February 21, 2018

OT:RR:CTF:VS: H284834 JMV

CATEGORY: Origin

George W. Thompson, Esq.
Thompson & Associates, PLLC
1250 Connecticut Ave. NW, Suite 200
Washington, DC, 20036

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Tablet Computers, CareConsole Hub and Mobile Hub

Dear Mr. Thompson:

This is in response to your letter of March 20, 2017, on behalf of 1Vision, LLC ("1Vision"), requesting a final determination concerning the country origin of a product that you refer to as the AMC Home Tele-health System ("Tele-health System" or "the System"), pursuant to subpart B of Part 177, U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. § 177.21, *et seq.*). You state in your letter that this request is being made pursuant to a contract with the Department of Veterans Affairs (VA) with 1Vision requiring the filing of a request for a country of origin determination from CBP.

As a domestic producer, 1Vision 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 products at issue are the Tele-health System in its entirety and the components, the CareConsole Hub and the Mobile Hub. The CareConsole Hub and the Mobile Hub, respectively, begin as a tablet computer and a smart phone. The CareConsole Hub is produced in the Republic of Korea and the Mobile Hub is produced in China. Both products are intended for purchase by the Veterans Health Administration for use by patients at home. The CareConsole Hub and the Mobile Hub are designed to collect health data that is measured by other peripheral devices, such as blood pressure cuffs, blood glucose monitors, etc. These other peripheral devices are not imported with the tablet and could be used "as is" within the 1Vision ecosystem, without any changes.

In the United States, the tablet and smart phone go through a number of software uninstallations and installations. The generic Android functions originally included on the

devices, such as alarms, calculators and text messaging, are removed. In order to enable the devices to function within the Tele-health System, other functions, such as Bluetooth capability, are modified and additional software is added. In addition, 1Vision also further processes the devices to include additional security mechanisms and to enable them to function in Plain Old Telephone Systems ("POTS"), an analog telephone service that continues to be the basic form of home and small business service connection to telephone networks.

Finally, the AMC CareConsole Mobile Application is installed on both devices. According to the information provided, this software was developed entirely in the United States. The software enables the patient to provide vital sign data by connecting to the peripheral devices via Bluetooth. The patient's information is then forwarded to VA clinicians over the VA intranet. This application is installed on the tablet to meet the VA's requirements for medical devices, including patient confidentiality and interoperability with VA systems and protocols. After the software installation is completed, the tablets cannot run any other program and cannot be reprogrammed to perform any other function.

The CareConsole Hub and Mobile Hub are then integrated into the Tele-health System, which also includes servers, data storage, networking, additional software, and health monitoring devices such as blood pressure cuffs and glucose monitors. The integration process consists of the CareConsole Hub or Mobile Hub contacting the Tele-health System, hosted in the VA data centers, which then sends an activation code and configuration file to the CareConsole Hub or Mobile Hub. The CareConsole Hub and Mobile Hub are then automatically configured to the peripheral health monitoring devices.

All the components, other than the CareConsole Hub and Mobile Hub, come from the United States, Mexico, Japan, Taiwan, Ireland, or the Republic of Korea. These components are customized as necessary to function in conjunction with each other. The CareConsole Hub and Mobile Hub collect information from the patients in their homes and transmit that data to the Tele-health System. The information is then presented to the VA Care Coordinators through the web application. The Tele-health System's various components are installed at multiple locations, including in the patients' homes, VA data centers and VA offices.

Like the Hub and Mobile Hub, the servers also cannot be used out of the box and must be customized. The servers are acquired without an operating system or software and are inoperable until software is installed. The servers are first installed at the VA Facility. The installation process takes five business days as it involves various assembling, configuring and testing processes. The final step is to load the AMC CareConsole software onto the servers.

ISSUE:

1. Whether the imported tablets and smart phones are substantially transformed by the uninstallation and installation of software in the United States, so as to make them a product of the United States.

2. Whether all the components of the Tele-health System are substantially transformed through the creation and installation of that system in the United States so as to make them a product of the United States.

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 rendering final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement 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 Trade Agreements Act. 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 name, character, or use distinct from that of the article or articles from which it was transformed." See 48 C.F.R § 25.003.

In *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that 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 the United States, the programming bestowed upon each integrated 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. The essence of the article, its interconnections or stored memory, was established by programming. *See also, Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982) (stating the substantial transformation issue is a "mixed question of technology and customs law"); HQ 735027, dated September 7, 1993 (programming blank media (EEPROM) with instructions that allow it to perform certain functions that prevent piracy of software constitutes a substantial transformation); and, HQ 734518, dated June 28, 1993 (motherboards are not substantially transformed by the implanting of the central processing unit on the board because, whereas in *Data General* use was being assigned to the PROM, the use of the motherboard had already been determined when the importer imported it).

"The term 'character' is defined as 'one of the essentials of structure, form, materials, or function that together make up and usually distinguish the individual.'" *National Hand Tool Corp. v. United States*, 16 C.I.T. 308, 311 (1992) (citing *Webster's Third New International Dictionary* (1981)). In *National Juice Prods. Ass'n v. United States*, the Court of International Trade applied the "essence test" and found that the fundamental character of orange juice concentrate was not changed by the addition of water, orange essences, and oils to make frozen concentrated orange juice, and hence, there was no substantial transformation. 10 C.I.T. 48, 628 F. Supp. 978 (1986).

HQ H258960, dated May 19, 2016, reviewed the country of origin of hardware components of certain transceivers in two scenarios that are instructive to the case at issue here. The hardware components of the transceivers were wholly manufactured in a foreign country and imported into the United States. In the first scenario, the transceivers were "blanks" and completely non-functional and specialized proprietary software was developed and downloaded in the United States, making the transceivers functional and compatible with the OEM technology. In the second scenario, the transceivers were preprogrammed with a generic program that was replaced with specialized proprietary software. It was argued that in both scenarios, the imported hardware was substantially transformed by the development, configuration, and downloading operations of the U.S. origin software. In the first scenario, we found that the non-functional transceivers were substantially transformed as a result of downloading performed in the United States, with proprietary software developed in the United States. However, in the second scenario, it was determined that since the transceivers had generic network functionality, programming them merely to customize their network compatibility would not actually change the identity of the imported transceivers. *See also* HQ H241177, dated December 3, 2013. Accordingly, it was determined that the country where the last substantial transformation occurred was China or another Asian country where the hardware components were manufactured.

In this case, you contend that the deletion of software and the installation of new software performed in the United States transform the generic tablet computers and smartphones into medical devices. You emphasize that the U.S. operations disable the Android applications and install health monitoring software, which, you argue, creates an entirely new purpose for the devices. You further stress the complexity and number of steps taken to transform the tablets and smartphones into devices that may be used within the Tele-health System. Therefore, you contend that this operation substantially transforms the tablets and smartphones into new medical devices with distinct names, characters and uses.

In essence, what is being done by the uninstallation and installation of software in the United States, is to limit the original capacity of the imported tablets and smartphones for the purpose of facilitating the reception, collection and transmission of a patient's medical data to VA clinicians for their review. The out-of-box tablets and smartphones have the ability to perform these general functions, but in order to meet the requirements outlined in the VA Request for Procurement, the CareConsole Hub and Mobile Hub are modified as discussed. In other words, when the tablets and smartphones are created, they have the ability to receive,

collect, and transmit data. The installed software merely enables these devices to receive and collect an individual patient's medical data from the peripheral devices and transmit this medical data to the clinicians at the VA.

It is clear that loading the specialized software onto a tablet computer or smartphone that remains fully functional as such would be insufficient to constitute a new and different article of commerce, since all of the functionality of the original device would be retained. In this case, however, in addition to adding the software, we are being asked to consider the effect of disabling the general applications that have been programmed onto the tablet and smartphone. In our judgment, this added factor does not cause or require a different result. The functions of the original tablet and smartphone produced in the Republic of Korea or China, necessary to receive and transmit data are in essence still present on the modified devices, as aided by the software. While the tablet and smartphone are no longer freely programmable machines, we find the imposition of this limitation is insufficient to constitute a substantial transformation of the imported tablets and smartphones.

Furthermore, we note that the converted tablets and smartphones loaded with the AMC CareConsole Application Software do not actually measure any health related functions, such as blood pressure, or oxygen saturation levels, nor do they provide any medical treatment to patients. Instead, the devices function to receive medical data that is obtained from other peripheral devices, such as a blood pressure cuff or an oxygen sensor, and to transmit that medical data to a clinician for review. Therefore, it appears that after the proprietary software is downloaded onto the tablets and smartphones, they function basically as a type of communications device.

In reviewing the processing performed in the United States on the imported tablets and smartphones under consideration, we note that it is analogous to the situation of the transceivers described by the second scenario of HQ H258960. The imported devices are preprogrammed with a generic program, which is the standard Android operating system, prior to their importation. When they are first imported, the tablets and smartphones can perform all of their standard functions of an android tablet or smartphone, and can in their imported condition be used for their intended purpose, but are customized for use within the VA Healthcare network. Accordingly, like the transceivers described in the second scenario of HQ H258960, we find that the name, character, and use of the imported devices remain the same. Therefore, we further find that the imported devices are not substantially transformed in the United States by the downloading of the proprietary software, which allows them to function with the VA Healthcare network. After the AMC CareConsole Application software is downloaded, the country of origin of the imported tablets and smartphones remains the country where they were originally manufactured, which in this case is the Republic of Korea and China, respectively.

The Tele-health System

In this situation, you also present an additional argument that the "end product" is an entire system that includes all hardware and software components, because it is defined as such

in the VA contract. The implication of this claim is that CBP should consider the Tele-health System as a whole in its substantial transformation analysis. The VA's determination on what is the "end product" is based upon different criteria from what CBP must consider in determining the country of origin of a product using the substantial transformation test. We note that the components at issue do not lose their individual identities and, therefore, are not substantially transformed into a new and different article.

In HQ H125975, dated January 19, 2011, which 1Vision cites in support of its argument, the LSI Engenio 7900 Data Storage System ("7900 System") was under consideration for government procurement purposes. The 7900 System was assembled in Mexico from components originating in various other nations. These parts included the Engenio Operating System, a controller assembly, a mounting assembly, a set of hard drives, a slot drive module assembly, and a cabinet assembly. Further, the controller assembly was reprogrammed with the EOS software to impart the functional intelligence to the 7900 System to allow for storage management, access control and performance monitoring. CBP found that as a result of the assembly and programming operations that took place in Mexico, the imported components of various origins lost their individual identities and were substantially transformed into a new and different article, that is, the 7900 System.

Although the CareConsole Hub, Mobile Hub and servers are customized to the VA contract specifications, the programming of each component to function in coordination with each other for a common purpose does not lead to a substantial transformation finding. As discussed above, the tablets and phones are not substantially transformed by the uninstallation and installation of software. Similarly, we cannot find a substantial transformation of the servers because software is installed. Moreover, the installation of the software onto the servers would not affect the other components of Tele-health System as they remain separate articles of commerce. Unlike the situation in H125975, all the devices and peripheral equipment remain identifiable as separate components. The peripheral medical devices, such as the blood pressure cuffs, blood glucose monitors etc., remain, as stated, "as is" and without any customization; the CareConsole Hub and Mobile Hub, as explained above, remain and continue to function as communication devices; the servers remain and continue to function as servers, etc. The fact that these devices are programmed to function in conjunction with each other for the purpose of receiving, collecting and transmitting medical data does not mean that a change of use or character occurs. Since the components have not lost their separate identities during assembly of the Tele-health System and have not become an integral part of a new and distinct item, which is visibly different from any of the individual components, we find there is no substantial transformation.

HOLDING:

Based on the facts of this case, the imported tablets and smartphones used with the CareConsole Hub and Mobile Hub platform are not substantially transformed by the installation of the AMC CareConsole Application. Therefore, the country of origin of the tablets and smartphones will remain the country where they were originally manufactured. Additionally, all components of the Tele-health System are not substantially transformed through the creation and installation of that system in the United States so as to make them a product of 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

HQ H284617

February 21, 2018

OT:RR:CTF:VS: H284617 JMV

CATEGORY: Origin

David E. Fletcher, Esq.
Cooley LLP
1299 Pennsylvania Avenue, NW Suite 700
Washington, DC 20004-2400

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Tablet Computers, Health Mobile and Hub Platforms

Dear Mr. Fletcher,

This is in response to your letter of March 21, 2017, on behalf of Care Innovations requesting a final determination concerning the country of origin of a product that you refer to as "the Hub Platform and the Mobile Platform," pursuant to subpart B of Part 177, U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. § 177.21, *et seq.*). You state in your letter that this request is being made pursuant to a letter from the Department of Veterans Affairs (VA) to Care Innovations requiring the filing of a request for a country of origin determination from CBP.

As a domestic importer of merchandise, Care Innovations 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 products at issue are referred to as the Hub Platform and the Mobile Platform. The Hub Platform is a home based platform that operates via Plain Old Telephone Systems ("POTS"), while the Mobile Platform is a handheld platform with wireless connectivity. Both platforms begin as iPad tablet computers that are produced by Apple in China, which are later encased with protective cases that are also manufactured in China. The tablet is designed for use by patients at home to collect health data that is measured by other peripheral devices such as blood pressure monitors, spirometer etc. These other devices are not imported with the tablet.

After the tablets are imported into the United States, Care Innovations performs additional production steps in its Roseville, California facility to create the Hub Platform and Mobile Platform. Care Innovations installs the Health Harmony Mobile software on the tablet computers, adds a Subscriber Identity Module ("SIM") card supplied by the cellular service provider, and packages the tablets in the protective cases. For the Hub Platform, which runs on POTS, Care Innovations attaches a POTS modem and router, manufactured in the United States with imported components. For both the Hub Platform and the Mobile Platform, Care Innovations installs the Airwatch Mobile Device Manager application, which removes the functionality usually available on an Apple iPad Mini tablet so that the user will only be able to run the Health Harmony Mobile software. The end result is a tablet locked into "single app mode," running only the Health Harmony application functionality and Bluetooth linked peripheral screens.

Care Innovations also adds physical asset tags to each tablet and registers them on Care Innovation's Mobile Device Management server; registers component details in the customer database; and verifies and documents the testing of the image and registered software. Care Innovations then packages the Hub Platform and Mobile Platform with the necessary licenses, privacy notices, and quick start guides. Finally, Care Innovations activates the platforms' features and prepares the platforms to be assigned to a specific end user.

ISSUE:

Whether the imported tablets are substantially transformed by the installation of Care Innovations' software, so as to make them a product of the United States.

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 rendering final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement 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 Trade Agreements Act. *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." *See* 48 C.F.R § 25.003.

In *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that 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 the United States, the programming bestowed upon each integrated 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. The essence of the article, its interconnections or stored memory, was established by programming. *See also, Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982) (stating the substantial transformation issue is a "mixed question of technology and customs law"); HQ 735027, dated September 7, 1993 (programming blank media (EEPROM) with instructions that allow it to perform certain functions that prevent piracy of software constitutes a substantial transformation); and HQ 734518, dated June 28, 1993 (motherboards are not substantially transformed by the implanting of the central processing unit on the board because, whereas in *Data General* use was being assigned to the PROM, the use of the motherboard had already been determined when the importer imported it).

"The term 'character' is defined as 'one of the essentials of structure, form, materials, or function that together make up and usually distinguish the individual.'" *National Hand Tool Corp. v. United States*, 16 C.I.T. 308, 311 (1992) (citing *Webster's Third New International Dictionary* (1981)). In *National Juice Prods. Ass'n v. United States*, the Court of International Trade applied the "essence test" and found that the fundamental character of orange juice concentrate was not changed by the addition of water, orange essences, and oils to make frozen concentrated orange juice, and hence, there was no substantial transformation. 10 C.I.T. 48, 628 F. Supp. 978 (1986).

HQ H258960, dated May 19, 2016, reviewed the country of origin of hardware components of certain transceivers in two scenarios that are instructive to the case at issue here. The hardware components of the transceivers were wholly manufactured in a foreign country and imported into the United States. In the first scenario, the transceivers were "blanks" and completely non-functional and specialized proprietary software was developed and downloaded in the United States, making the transceivers functional and compatible with the OEM technology. In the second scenario, the transceivers were preprogrammed with a generic program that was replaced with specialized proprietary software. It was argued that in both scenarios, the imported hardware was substantially transformed by the development, configuration, and downloading operations of the U.S. origin software. In the first scenario, we found that the non-functional transceivers were substantially transformed as a result of downloading performed in the United States, with proprietary software developed in the United States. However, in the second scenario, it was determined that since the transceivers had generic network functionality, programming them merely to customize their network compatibility would not actually change the identity of the imported transceivers. *See also* HQ H241177, dated December 3, 2013. Accordingly, it was determined that the country where the last substantial transformation occurred was China or another Asian country where the hardware components were manufactured.

In this case, you assert that the software downloading operations performed in the United States transform the generic tablet computers into medical devices. You further argue that the tablets undergo a complex production process performed by skilled production associates at Care Innovations' Roseville, California facility. You emphasize that the U.S. operations disable the generic Apple iPad applications and install health monitoring software that cannot be undone by third parties during the normal course of operations. Therefore, you contend that this operation substantially transforms the Apple iPad tablet into a new medical device with a distinct name, character and use.

In essence, what is being done by the installation of the software in the United States, is to limit the original capacity of the imported tablets for the purpose of facilitating the reception, collection and transmission of a patient's medical data to VA clinicians for their review. The original tablet has the ability to perform these functions, but it was determined that in order to meet FDA regulations, it is best to disable the various functions of the tablet and to replace them with one function via the specialized software. In other words, when the tablets are created, they have the ability to receive, collect, and transmit data. The installed software just enables the tablets to receive and collect an individual patient's medical data from the peripheral devices and transmit this medical data to the clinicians at the VA.

It is clear that loading specialized software onto the tablet computer that remains fully functional as a computer would be insufficient to constitute a new and different article of commerce, since all of the functionality of the original computer would be retained. In this case, however, in addition to adding the software, we are being asked to consider the effect of disabling the general applications that have been programmed onto the tablet. In our judgment, this added factor does not cause or require a different result. The functions of the original tablet

produced in China that are necessary to receive and transmit data are in essence still present on the modified tablet, as aided by the software. While the tablet is no longer a freely programmable machine, we find the imposition of this limitation is insufficient to constitute a substantial transformation of the imported tablets in the United States.

Furthermore, we note that the converted tablets loaded with the Health Harmony software do not actually measure any health related functions, such as blood pressure, or oxygen saturation levels, nor do they provide any medical treatment to patients. Instead, the converted tablets function to receive medical data that is obtained from other peripheral devices, such as a blood pressure monitor or pulse oximeter, and to transmit that medical data to a clinician for review. Therefore, it appears that after the proprietary software is downloaded onto the tablets, the tablets continue to basically function as a type of communications device.

It is also claimed that the FDA considers the Hub Platform and the Mobile Platform to be medical devices and that the IRS will tax the Health Harmony system, including the tablet, as a medical device. Thus, you contend that CBP should also consider the tablets loaded with the Health Harmony software to be medical devices rather than tablets. We note, however, that the IRS and FDA's determinations as to whether any items are considered medical devices are based upon different criteria from what CBP must apply in determining the country of origin of a product using the substantial transformation test. In HQ H019436, dated March 17, 2008, CBP considered the tariff classification of a SONA Sleep Apnea Avoidance Pillow imported from China. The ruling noted that while the subject merchandise was considered a Class II therapeutic cervical pillow for snoring and mild sleep apnea by the FDA, this determination did not control tariff classification. Similarly in this case, the IRS and FDA's determinations that the imported tablets are medical devices and will be taxed as such are of limited relevance to CBP's determination as to the country of origin of the devices.

In reviewing the processing performed in the United States on the imported tablets under consideration, we note that it is analogous to the situation of the transceivers described by the second scenario of HQ H258960. The imported tablets are preprogrammed with a generic program, which is the standard Apple iPad operating system, prior to their importation. When they are first imported, the tablets can perform all of the standard functions of an Apple iPad tablet, and can in their imported condition be used in conjunction with the proprietary software. Accordingly, like the transceivers described in the second scenario of HQ H258960, we find that the name, character, and use of the imported tablet computers remain the same. Therefore, we further find that the imported tablets are not substantially transformed in the United States by the downloading of the proprietary software, which allows them to function within the VA Healthcare network. After the Health Harmony software is downloaded, the country of origin of the imported tablets remains the country where they were originally manufactured, which in this case is China.

Finally, you argue that since CBP concluded that a predecessor of the Health Harmony System, Stehekin, was considered part of a patient monitoring system rather than a standard computer in NY Ruling N004877 dated January 26, 2007, it would be inconsistent to conclude that Health Harmony, as Stehekin's descendant, is, for purposes of government procurement,

merely a "standard computer" manufactured outside the United States. You claim that Stehekin is analogous to the tablet computer that Care Innovations uses today because it included a purpose-built computer, produced in China, that was used to deliver remote patient monitoring software and capability. However, the issue decided in N004877 was a question of tariff classification, not substantial transformation, and is therefore, not applicable.

HOLDING:

Based on the facts of this case, the imported tablets used with the Mobile Platform and the Hub platform are not substantially transformed by the installation of the proprietary Health Harmony software. Therefore, the country of origin of the tablets will remain the country where they were originally manufactured.

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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