

in accordance with the Accomplishment Instructions, paragraph A.4., in Viking SB V6/0063, Revision A, and the Accomplishment Instructions, Sections A through C, in Viking DHC-6 Twin Otter Technical Bulletin No. V6/00155, Revision NC, dated September 14, 2020 (Viking TB V6/00155, Revision NC).

(ii) If there is no binding and no restriction, before further flight, remove each affected FCU push rod assembly, clean the push rod ends, and inspect each affected FCU push rod assembly for corrosion and condition of the lubricant. Pay particular attention to the bearing ball and race.

(A) If there is no corrosion and the lubricant color and texture is normal, before further flight, lubricate each affected FCU push rod assembly in accordance with the Accomplishment Instructions, Section C, in Viking SB V6/0063, Revision A.

(B) If there is corrosion or if the lubricant is abnormal in color (too dark) or texture (too sticky), before further flight, remove both affected FCU push rod assemblies from service and install serviceable FCU push rod assemblies in accordance with the Accomplishment Instructions, paragraph A.4, in Viking SB V6/0063, Revision A, and the Accomplishment Instructions, Sections A through C, in Viking TB V6/00155, Revision NC.

(2) Repeat the requirements of this AD as follows until both affected FCU push rod assemblies are replaced.

(i) Test and lubrication: At intervals not to exceed 125 hours TIS or before further flight anytime the airplane has not been operated for a period of 30 days, whichever occurs first.

(ii) Inspection: At intervals not to exceed 1,500 hours TIS.

(3) As of the effective date of this AD, do not install an affected FCU push rod assembly on any airplane.

(i) Credit for Previous Actions

You may take credit for the test, inspection, replacement, and lubrication required by paragraphs (h)(1) and (2) of this AD if you performed those actions before the effective date of this AD using Viking DHC-6 Twin Otter Service Bulletin No. V6/0063, Revision NC, dated June 7, 2019.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact Elizabeth Dowling, Aviation Safety

Engineer, New York ACO Branch, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228-7300; email: elizabeth.m.dowling@faa.gov.

(2) Refer to Transport Canada AD CF-2021-42, dated November 26, 2021, for more information. You may examine the Transport Canada AD in the AD docket at <https://www.regulations.gov> by searching for and locating it in Docket No. FAA-2022-0284.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Viking DHC-6 Twin Otter Service Bulletin No. V6/0063, Revision A, dated February 1, 2021.

(ii) Viking DHC-6 Twin Otter Technical Bulletin No. V6/00155, Revision NC, dated September 14, 2020.

(3) For service information identified in this AD, contact Viking Air Ltd., 1959 de Havilland Way, Sidney British Columbia, Canada V8L 5V5; phone: (800) 663-8444; email: continuing.airworthiness@vikingair.com; website: <https://www.vikingair.com>.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on May 24, 2022.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 22-11]

RIN 1515-AE73

Extension of Import Restrictions Imposed on Certain Archaeological Artifacts and Ethnological Material From Peru

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

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect an extension of import restrictions on certain categories of archaeological artifacts and ethnological material of the Republic of Peru. The restrictions, which were originally imposed by Treasury Decision (T.D.) 97-50 and last extended by CBP Decision (CBP Dec.) 17-03, are due to expire on June 9, 2022, unless extended. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for extending the import restrictions that previously existed and no cause for suspension exists. Pursuant to the exchange of diplomatic notes to extend the agreement, the import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this further extension through June 8, 2027. CBP-Dec. 17-03 contains the Designated List of archeological artifacts and ethnological material from Peru to which the restrictions apply.

DATES: Effective on June 9, 2022.

FOR FURTHER INFORMATION CONTACT: For legal aspects, W. Richmond Beevers, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325-0084, ot-trrculturalproperty@cbp.dhs.gov. For operational aspects, Julie L. Stoeber, Chief, 1USG Branch, Trade Policy and Programs, Office of Trade, (202) 945-7064, 1USGBranch@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Convention on Cultural Property Implementation Act, Public Law 97-446, 19 U.S.C. 2601 *et seq.*, which implements the 1970 United

Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)), the United States entered into a bilateral agreement with the Republic of Peru (Peru) on June 9, 1997, concerning the imposition of import restrictions on archaeological material from the Pre-Hispanic cultures and certain ethnological material from the Colonial period of Peru (the Memorandum of Understanding (MOU) between the United States of America and the Republic of Peru).

On June 11, 1997, the U.S. Customs Service (U.S. Customs and Border Protection's predecessor agency) published Treasury Decision (T.D.) 97–50 in the **Federal Register** (62 FR 31713), which amended § 12.104g(a) of title 19 of the Code of Federal Regulations (19 CFR 12.104g(a)) to reflect the imposition of these restrictions and included a list designating the types of archaeological and ethnological material covered by the restrictions. These restrictions continued the protection of archaeological material from the Sipán Archaeological Region forming part of the remains of the Moche culture that were first subject to emergency import restrictions on May 7, 1990 (T.D. 90–37), which were extended on June 27, 1994 (T.D. 94–54).

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period may be extended for additional periods of no more than five years if it is determined that the factors which justified the agreement still pertain and no cause for suspension of the agreement exists. *See* 19 CFR 12.104g(a).

Since the initial final rule was published on June 11, 1997, the import restrictions were subsequently extended four (4) times. First, on June 6, 2002, following the exchange of diplomatic notes, the former U.S. Customs Service published a final rule (T.D. 02–30) in the **Federal Register** (67 FR 38877) to extend the import restrictions for a period of five years. Second, on June 6, 2007, following the exchange of diplomatic notes, CBP published a final rule (CBP Dec. 07–27) in the **Federal Register** (72 FR 31176) to extend the import restrictions for an additional five-year period. Third, on June 7, 2012, following the exchange of diplomatic notes, CBP published a final rule (CBP

Dec. 12–11) in the **Federal Register** (77 FR 33624) to extend the import restrictions for an additional five-year period. Fourth and lastly, on June 7, 2017, following the exchange of diplomatic notes, CBP published a final rule (CBP Dec. 17–03) in the **Federal Register** (82 FR 26340) to extend the import restrictions for an additional five-year period through June 8, 2022.

On September 13, 2021, the United States Department of State proposed in the **Federal Register** (86 FR 50931) to extend the MOU between the United States and Peru concerning the import restrictions on certain categories of archaeological and ethnological material from Peru. On March 15, 2022, after consultation with and recommendations by the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, determined that the cultural heritage of Peru continues to be in jeopardy from pillage of certain archeological and ethnological material, and that the import restrictions should be extended for an additional five years. Pursuant to the exchange of diplomatic notes to extend the agreement, the import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this further extension through June 8, 2027.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The restrictions on the importation of archaeological artifacts and ethnological material are to continue to be in effect through June 8, 2027. Importation of such material from Peru continues to be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: <https://eca.state.gov/cultural-heritage-center/cultural-property-advisory-committee/current-import-restrictions> by selecting the material for “Peru.”

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions

of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1), pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

Chris Magnus, the Commissioner of CBP, having reviewed and approved this document, has delegated the authority to electronically sign this document to Robert F. Alneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

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■ 2. In § 12.104g, amend the table in paragraph (a) by revising the entry for Peru to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
* * * * *	* * * * *	* * * * *
Peru	Archaeological artifacts and ethnological material from Peru	CBP Dec. 22–11.
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Robert F. Altneu,

*Director, Regulations & Disclosure Law
Division, Regulations & Rulings, Office of
Trade, U.S. Customs and Border Protection.*

Approved:

Thomas C. West Jr.,

*Deputy Assistant Secretary of the Treasury
for Tax Policy.*

[FR Doc. 2022–12299 Filed 6–7–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2021–N–0600]

Medical Devices; Cardiovascular Devices; Classification of the Intravascular Bleed Monitor

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the intravascular bleed monitor into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intravascular bleed monitor's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective June 8, 2022. The classification was applicable on March 1, 2019.

FOR FURTHER INFORMATION CONTACT: LT Stephen Browning, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2106, Silver Spring, MD 20993–0002, 240–402–5241, Stephen.Browning@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the intravascular bleed monitor as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 23, 2018, Saranas, Inc. submitted a request for De Novo classification of the Early Bird Bleed Monitoring System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for